European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

COMMITTEE OF EXPERTS ON THE CLASSIFICATION OF MEDICINES AS REGARDS THEIR SUPPLY (CD-P-PH/PHO)

Report classification/justification of

- Medicines belonging to the ATC group D07 (Corticosteroids, Dermatological Preparations)

- Triamcinolone

(ATC codes: A01AC01; C05AA12; D07BB03; D07CB01; D07XB02; H02AB08; R01AD11; R03BA06; S01BA05; S02CA04)

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INTRODUCTION

The legal classification of medicines as regards their supply with or without a medical prescription has implications for patient safety, patient accessibility to medicines and the responsible management of healthcare expenditure.

For many years, the **Council of Europe** (**which is distinct from the European Union**)[1] has been concerned with the supply conditions of medicines for human use and the harmonisation of national legal provisions from the perspective of patient safety and public health protection. An initial Recommendation AP(61)2 was drawn up in 1961 to control a growing tendency of misuse and overuse of sedative and narcotic medicines by empowering the competent authorities to classify new medicines into prescription and non-prescription medicines, taking into consideration the risks associated with the active substance and the conditions of use of the medicines.

On 12 April 2007, the Council of Europe Committee of Ministers adopted Resolution ResAP (2007)1 on the classification of medicines as regards their supply[2]. The resolution is aimed at promoting patient safety and improving patient accessibility to medicines, and is focused on public health. The resolution:

> "*1. Recommends to the governments of the member states of the Partial Agreement in the Social and Public Health Field that they supply information on the national legal classification of medicines as regards their supply on a regular basis;*
>
> *2. Recommends to the same governments that they apply the general provisions and the classification of active substances depending on the supply conditions of the medicines which contain them,* ***as set out in the appendices***."

The text of this Council of Europe resolution comprises a recommendation of the Committee of Ministers (Foreign Affairs Ministers, representing the governments of states participating in an activity) to member states to implement the stipulations of the resolution into national legislation or to adapt national legislation.

Although recommendations are not legally binding, they are legal instruments; they may create soft law and contain a statement of policy. The Committee of Ministers may also invite the member states to report on their efforts to implement a recommendation.

As regards national licenses, industry is impacted if national authorities implement the revisions, as applicable.

It has to be borne in mind that the decisions of the Committee of Experts CD-P-PH/PHO as regards the supply of medications with or without a medical prescription, take into account national assessments and scientific rationale. Revisions are completed and made available following each second annual meeting of the Committee of Experts on the classification of medicines as regards their supply (CD-P-PH/PHO) (Appendices 2011, ResAP (2007)1).

The annually revised appendices of the Council of Europe Resolution ResAP (2007)1 on the classification of medicines as regards their supply provide a key source of reference for the European pharmaceutical industry.

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[1] www.coe.int

[2] https://go.edqm.eu/ResAP20071

The classification criteria set out in the Council of Europe resolutions have been included in **European Union** legislation, such as Directive 92/26/EC and Directive 2001/83/EC (art. 70-75). In the preamble of Directive 2001/83/EC (see point 32), reference is made to the Council of Europe: "*It is therefore appropriate, as an initial step, to harmonise the basic principles applicable to the classification for the supply of medicinal products in the Community or in the Member State concerned, while taking as a starting point the principles already established on this subject by the Council of Europe*[3]."

To date, the classification of medicines remains a competency of states in Europe. This also holds true for the member states of the European Union.

The Committee of Experts on the classification of medicines as regards their supply (CD-P-PH/PHO), which is co-ordinated by the European Directorate for the Quality of Medicines & HealthCare (EDQM, Council of Europe), does not issue recommendations on the classification of particular medicines, but on **active substances used in a medicine for a specific therapeutic purpose**. The Committee of Experts CD-P-PH/PHO reviews the classification of medicines (INN/ATC[4]) authorised in Europe via national and European marketing authorisation procedures (the latter is applicable to the 47 Council of Europe member states, including the European Union member states) in order to establish recommendations for the classification of medicines (INN/ATC) and their supply conditions (see also Glossary of Terms, page 9), involving:

- Medicines that have not yet been included in Council of Europe recommendations;

- Medicines that qualify to be released from prescription status, i.e. a switch to "over the counter" (OTC) status or vice-versa;

- Revisions of current classifications.

The Committee of Experts CD-P-PH/PHO meets twice annually to finalise the annual review of the recommendations and appendices of ResAP (2007)1. The review is completed at the second of these meetings and is published on the website of the EDQM. These recommendations are an integral part of the Council of Europe's Committee of Ministers Resolution ResAP (2007)1 on the classification of medicines as regards their supply.

The Committee of Experts does not give advice relating to pending marketing authorisation procedures. It uses scientific approaches and methods (taking into account the pharmacological properties of the medicines), and considers issues relating to direct and indirect risks (pharmacovigilance), as well as misuse/abuse and matters of public health concern.

In its work, the CD-P-PH/PHO uses the Anatomical Therapeutic Chemical (ATC) classification maintained by the WHO Collaborating Centre for Drug Statistics Methodology[5]. The Commission of the European Union is entitled to participate in the meetings of the CD-P-PH/PHO.

[3] http://goo.gl/Uy22V1

[4] INN: International non-proprietary name; ATC: Anatomical Therapeutic Chemical (ATC) classification

[5] http://www.whocc.no/atc_ddd_index/

DISCLAIMER

This document is published for information only. The reports included in this document have no legal status and no binding character.

They reflect the conclusions of the reports arising from reviews of scientific classifications of medicines and the rationale and debates on which the recommendations on the classification of medicines as regards their supply, taken by the CD-P-PH/PHO at its 56th meeting on 11-12 March 2014 and its 57th meeting on 18-19 November 2014, were based. The document was reviewed and endorsed by the CD-P-PH/PHO at its 60th meeting on 19-20 April 2016.

The reviews carried out do not commit the parent authorities of the experts nor the Council of Europe/EDQM.

GLOSSARY OF TERMS USED IN THIS DOCUMENT

ACTH	Adrenocorticotropic hormone
ATC	Anatomical Therapeutic Chemical[6] classification
eMC	Electronic Medicines Compendium
HPA	Hypothalamic-pituitary-adrenal
INN	International non-proprietary name
MS	Maximal strength
MDD	Maximal daily dose
MQP	Maximal quantity per pack
OTC	Over-the-counter (medicine supplied without prescription)
PDR	Physicians' Desk Reference (www.pdr.net/)
POM	Prescription only medicine

Classification used throughout this document

Following the stipulations of Resolution ResAP (2007)1, the medicine contains one or more active substances classified as **List I** or **List II** to which the following criteria apply:

List I
The supply of a medicine containing one of the substances on this list may only be repeated if the prescriber specifies so on the prescription;

List II
The supply of a medicine containing one of the substances on this list may be repeated without the prescriber having specified so, provided that he/she did not explicitly forbid such repetition and that the amount supplied at renewals (and their frequency) be consistent with medical and pharmaceutical data (such as the prescribed daily dose, the duration of treatment, the degree of medical supervision required by the condition, etc.);

Exemptions from Lists I and II
- For certain substances, exemptions from the "prescription only" requirement may appear in Lists I and II:
    - In respect of a low dosage or concentration of the active substances and/or therapeutic indications of the medicines in which they are contained;
    - According to the route of administration and the composition of the medicine;
    - According to the total content of the medicine per container.

- Active substances classified according to the conditions of supply of the medicines which contain them as supplied without prescription, i.e. over-the-counter (OTC) medicines.

Medicines not subject to prescription (OTC medicines)
Active substances of medicines that are classified as not subject to prescription according to the criteria given in item 4 of the General Provisions of ResAP (2007)1 are classified in the list "Medicines not subject to prescription (OTC medicines)".

For the purpose of this resolution, OTC medicines are understood to be those also having a valid marketing authorisation issued by a competent authority.

[6] WHO Collaborating Centre for Drug Statistics Methodology - http://www.whocc.no/atc_ddd_index/

It is possible that a given active substance can be contained in both an OTC medicine and a medicine subject to prescription of the same ATC (Anatomical Therapeutic Chemical Classification) because of the particular conditions of use of the medicines in question.

General criteria for classification in the lists:

a. List I

1. Active substances of medicines indicated for conditions calling for short-term treatment and/or for which continuous medical supervision is necessary, either because of potential undesirable effects or to check the efficacy of treatment;

2. Active substances of medicines administered for diagnostic purposes;

3. Active substances with a new pharmacological mechanism of action.

b. List II

Active substances of medicines indicated for conditions for which the patient may continue regular or intermittent treatment without new medical advice, and for which well-known undesirable effects do not call for frequent clinical examinations.

c. List of OTC medicines

(see above).

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Triamcinolone

1.2 ATC Code: A01AC01 - Stomatological preparations, corticosteroids for local oral treatment

1.3 Therapeutic indications: treatment of symptoms associated with oral inflammatory lesions and ulcerative lesions resulting from trauma.

1.4 Posology and duration of treatment: dental paste - apply a thin film to the affected area, preferably at bedtime.

1.5 Pharmaceutical forms: paste

1.6 Contraindications: hypersensitivity to triamcinolone; presence of fungal, viral or bacterial infections of the mouth or throat.

1.7 Relevant warnings: if irritation develops, the treatment should be discontinued and appropriate therapy instituted. If concomitant mucosal infections are present or develop, an appropriate anti-fungal or anti-bacterial agent should be used. If significant regeneration or repair of oral tissues has not occurred in seven days, additional investigation into the aetiology of the oral lesion is advised. Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycaemia, glycosuria and other adverse effects known to occur with parenterally-administered steroid preparations. Therefore, it may be advisable to periodically evaluate patients on prolonged corticosteroid-containing dental paste therapy for evidence of HPA axis suppression. If HPA axis suppression is noted, use of the drug should be discontinued or the frequency of application should be reduced. Recovery of HPA axis function is generally prompt and complete upon discontinuation of therapy.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): the following local adverse reactions may occur: burning, itching, irritation, dryness, blistering or peeling, peri-oral dermatitis, allergic contact dermatitis, maceration of the oral mucosa, secondary infection and atrophy of the oral mucosa.

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I + exemption Annex III	Oropharyngeal	Warning: not for children	0.1%		
Austria (AT)	I (1)		As for all corticosteroids			
Belgium (BE)	Not authorised					
Czech Republic (CZ)	Not authorised					
Spain (ES)	II					
Finland (FI)	OTC, see Annex III					
France (FR)	Not authorised					
Croatia (HR)	Not authorised					
Italy (IT)	Not authorised					
Former Yugoslav Republic of	Not authorised					

Macedonia (MK)						
Poland (PL)	Not authorised					
Portugal (PT)	OTC, see Annex III					
United Kingdom (UK)	I + exemption Annex III		Treatment of common mouth ulcers. Maximum treatment period: 5 days. Check age and duration of treatment for children.	0.1%		5 g

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I + Exemption Annex III

Exemptions:

- Administration route: oropharyngeal;
- Adults only;
- Short-term use – maximum 5 days;
- MS: 0.5%.

Criteria:
Therapeutic indications
Safety profile

3.2 Paediatric use: not recommended to be used in children

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
Electronic Medicines Compendium (eMC) (Available at: http://www.medicines.org.uk/emc/)
Physicians' Desk Reference (PDR) online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Triamcinolone

1.2 ATC Code: C05AA12 - Agents for treatment of haemorrhoids and anal fissures for topical use, corticosteroids

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions: no data in *Melclass* database.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Methylprednisolone

1.2 ATC Code: D07AA01 - Corticosteroids, plain; corticosteroids, weak (group I)

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I	Cutaneous				
AT	Not authorised					
BE	Not authorised					
Switzerland (CH)	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
Ireland (IE)	Not authorised					
IT	Not authorised					
Lithuania (LT)	Not authorised					
MK	Not authorised					
PL	Not authorised					
RO	Not authorised					
UK	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Hydrocortisone

1.2 ATC Code: D07AA02 - Corticosteroids, plain; corticosteroids, weak (group I)

1.3 Therapeutic indications: treatment of a wide variety of dermatological conditions, including the following: eczema and dermatitis of all types including atopic eczema, photodermatitis, intertrigo, primary irritant and allergic dermatitis, prurigo nodularis, seborrhoeic dermatitis and insect bite reactions.

1.4 Posology and duration of treatment: apply, once to four times daily, gradually increasing the intervals between applications as the condition improves. Treatment may then be reduced to two to three times a week or when symptoms recur.

1.5 Pharmaceutical forms: cream/ointment

1.6 Contraindications: bacterial (e.g. impetigo), viral (e.g. Herpes simplex) or fungal (e.g. candidal or dermatophyte) infections of the skin; hypersensitivity to hydrocortisone; use on the eyes and face, ano-genital region, broken or infected skin including cold sores, acne and athlete's foot.

1.7 Relevant warnings: topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses following development of tolerance, risk of generalised pustular psoriasis, and local and systematic toxicity due to impaired barrier function of the skin. Careful patient supervision is important. Although generally regarded as safe even for long-term administration in adults, there is potential for overdosage in infants and children. Extreme caution is required in dermatoses of infancy especially napkin eruption where the napkin can act as an occlusive dressing and increase absorption. In infants and children, courses of treatment should therefore not normally exceed 7 days. Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions, which have become infected. Any spread of infection requires withdrawal of topical corticosteroid therapy, and a systemic administration of antimicrobial agents. As with all corticosteroids, prolonged application to the face is undesirable.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): adverse reactions: local atrophic changes may occur, particularly in skin folds, intertriginous areas or in nappy areas in young children where moist conditions favour hydrocortisone absorption. Systemic absorption from such sites may be sufficient to produce hypercorticism and suppression of the pituitary adrenal axis after prolonged treatment. This effect is more likely to occur in infants and children and if occlusive dressings are used or large areas of skin treated. Napkins may act as occlusive dressings.

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I (1) + exemption Annex III	Cutaneous	Max pack-size: 15 g	1%		150mg
AT	I					
BE	OTC, see Annex III	Cutaneous		1%		300mg
Bulgaria (BG)	II					
CH	II + exemption Annex III	Cutaneous				5 mg
CZ	OTC, see Annex III	Cutaneous		1%		100mg
Germany (DE)	I (1) + exemption Annex III	Cutaneous	inflammatory or allergic dermatoses (mild, moderate) for short term use (max. 2	0.5%		30 g

			weeks)			
DK	II + exemption Annex III			1%		
ES	OTC, see Annex III	Cutaneous		1%		
FI	OTC, see Annex III					
FR	II+ exemption Annex III	Cutaneous	List I: psoriasis, lichens, pruritus, dermatitis, eczema; OTC: for treatment of insect or nettle stings and sunburns	OTC: MS: 0.5%	MDD: 2 applications/day	75 mg
HR	I					
IE	II + exemption Annex III	Cutaneous	For irritant dermatitis, contact allergic dermatitis, insect bite reactions, mild to moderate eczema in adults and children not under 10 years.	1%		15 g
IT	OTC, see Annex III	Cutaneous		0.5%		
LV	I					
MK	I			2.5%		5 g
Netherlands (NL)	POM					
Norway (NO)	II + exemption Annex III	Cutaneous	Ointment and cream 25g containing up to 1% active ingredient	1%		25 g
PL	I + exemption Annex III	Cutaneous	No longer than 2 weeks; Prescription product: MS: 1% few times/day; OTC: MS: 0.5% 2-4 times/day	0.5 – 1%		15 – 20g
RO	I (1)					
Sweden (SE)	II					
Slovenia (SI)	II					
UK	II + exemption Annex III	Cutaneous	For use as a cream, ointment or spray either alone or in conjunction with crotamiton in irritant dermatitis, contact allergic dermatitis, insect bite reactions, mild to moderate eczema	1%		

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I + exemption Annex III

Exemptions:

- Not for large surfaces;
- Adults only;
- Maximum treatment duration: 7 days;
- Indications: contact allergic dermatitis, insect bite reactions;
- MS: 1%;
- MQP: 150 mg;
- Max 15 g pack (due to indications).

Criteria:
Danger of systemic absorption
Atrophy of the skin

3.2 Paediatric use: in infants and children, courses of treatment should not exceed 7 days.

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Prednisolone

1.2 ATC Code: D07AA03 - Corticosteroids, plain; corticosteroids, weak (group I)

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I (1)	Cutaneous				
AT	I (1)					
BE	Not authorised					
CH	II					
CZ	Not authorised					
ES	Not authorised					
FI	Not authorised					
FR	Not authorised					
IE	Not authorised					
IT	Not authorised					
LV	I (1)					
MK	Not authorised					
PL	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Clobetasone

1.2 ATC Code: D07AB01 - Corticosteroids, plain; corticosteroids, moderately potent (group II)

1.3 Therapeutic indications: treatment of eczema and dermatitis of all types including atopic eczema, photodermatitis, otitis externa, primary irritant and allergic dermatitis (including napkin rash), intertrigo, prurigo nodularis, seborrhoeic dermatitis and insect bite reactions. It may be used as maintenance therapy between courses of one of the more active topical steroids.

1.4 Posology and duration of treatment: for all ages: 0,05% w/w cream/ointment should be applied to the affected area up to four times a day until improvement occurs, when the frequency of application may be reduced.

1.5 Pharmaceutical forms: cream/ointment

1.6 Contraindications: skin lesions caused by infection with viruses (e.g. herpes simplex, chickenpox), fungi (e.g. candidiasis, tinea) or bacteria (e.g. impetigo); hypersensitivity to the clobetasone.

1.7 Relevant warnings: although generally regarded as safe, even for long-term administration in adults, there is a potential for overdosage, and in infants and children this may result in adrenal suppression. Extreme caution is required in dermatoses in such patients and treatment should not normally exceed seven days. In infants, the napkin may act as an occlusive dressing, and increase absorption. Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions which have become infected. Any spread of infection requires withdrawal of topical corticosteroid therapy, and systemic administration of antimicrobial agents. As with all corticosteroids, prolonged application to the face is undesirable. Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses, development of tolerance, risk of generalised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin. If used in psoriasis, careful patient supervision is important. If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye as glaucoma might result.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance):

Adverse reactions:

Immune System Disorders
Very rare: hypersensitivity. Local hypersensitivity reactions such as erythema, rash, pruritus, urticaria, local skin burning and allergic contact dermatitis may occur at the site of application and may resemble symptoms of the condition under treatment. In the unlikely event of signs of hypersensitivity appearing, application should stop immediately.

Endocrine Disorders
Very rare: adrenal suppression
When large areas of the body are being treated with clobetasone, it is possible that some patients will absorb sufficient steroid to cause transient adrenal suppression despite the low degree of systemic activity associated with clobetasone.

Skin and Subcutaneous Tissue Disorders
Very rare: skin atrophy, pigmentation changes, hypertrichosis.
Local atrophic changes could possibly occur in situations where moisture increases absorption of clobetasone butyrate, but only after prolonged use.

General Disorders and Administration Site Conditions: Very rare: exacerbation of underlying symptoms

2.1.1 Recent cases at European level: no data available

2.1.2 Indirect risks (incorrect use): no data available

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I	Cutaneous				
AT	Not authorised					
BE	Not authorised					
BG	II					
CH	II					
CZ	Not authorised					
ES	POM					
FI	POM					
FR	Not authorised					
IE	Not authorised					
IT	II + exemption Annex III	Cutaneous				7.5 mg
MK	Not authorised					
PL	Not authorised					
PT	II					
SE	II					
UK	II + exemption Annex III	Cutaneous		0.05 mg		15 g

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I

Criteria:
Therapeutic indications
Safety profile

3.2 Paediatric use: in infants and children, courses of treatment should not exceed 7 days.

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Hydrocortisone butyrate

1.2 ATC Code: D07AB02 - Corticosteroids, plain; corticosteroids, moderately potent (group II)

1.3 Therapeutic indications:
Cream/ointment: treatment of conditions responsive to topical corticosteroids e.g. eczema, dermatitis and psoriasis. Topical corticosteroids are not generally indicated in psoriasis but may be acceptable in psoriasis, excluding widespread plaque psoriasis, provided warnings are given.

Scalp lotion: treatment of scalp conditions responsive to topical corticosteroids, e.g. eczema, dermatitis and psoriasis.

1.4 Posology and duration of treatment: for topical application.
Dosage: To be applied evenly and sparingly not more than twice daily. Application of cream/ointment may be made under occlusion in the more resistant lesions such as thickened psoriatic plaques on elbows and knees.
Adults and elderly: The same dose is used for adults and the elderly, as clinical evidence would indicate that no special dosage regimen is necessary in the elderly.

1.5 Pharmaceutical forms: cream/ointment/scalp lotion

1.6 Contraindications: hypersensitivity to hydrocortisone; in the presence of untreated viral or fungal infections, tubercular or syphilitic lesions, peri-oral dermatitis, acne vulgaris and rosacea and in bacterial infections unless used in connection with appropriate chemotherapy.

1.7 Relevant warnings: although generally regarded as safe, even for long-term administration in adults, there is a potential for adverse effects if overused in infancy. Extreme caution is required in dermatoses of infancy. In such patients courses of treatment should not normally exceed 7 days. As with all corticosteroids, application to the face, flexures and other areas of thin skin may cause skin atrophy and increased absorption and should be avoided. Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses following development of tolerance, risk of generalised pustular psoriasis and local and systemic toxicity due to impaired barrier function of the skin. Steroids may have a place in treating psoriasis of the scalp and chronic plaque psoriasis of the hands and feet. Careful patient supervision is important.
Contact with the eyes should be avoided.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance):

Adverse reactions:

Immune system disorders
Not known: hypersensitivity

Endocrine disorders
Very rare: adrenal suppression

Skin and subcutaneous tissue disorders: rare: skin atrophy, often irreversible, with thinning of the epidermis, telangiectasia, skin striae, pustular acne, perioral dermatitis, rebound effect, skin depigmentation, dermatitis and eczema, including contact dermatitis

2.1.1 Recent cases at European level: not known.

2.1.2 Indirect risks (incorrect use): excessive use under occlusive dressings may produce adrenal suppression.

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I					
AT	Not authorised					
BE	Not authorised					
CZ	I					
ES	POM					
FR	I					
HR	Not authorised					
IE	II					
IT	II	Cutaneous				7.5 mg
MK	Not authorised					
PL	I	Cutaneous	Do not use longer than 2 weeks; Cream and ointment: MQP: 15 mg, Liquid form: MQP: 30 mg	0.1%		30 mg
RO	I					
SI	I					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I

Criteria:
Therapeutic indications
Safety profile

3.2 Paediatric use: *Children*: long term treatment should be avoided where possible. *Infants*: therapy should be limited if possible to a maximum of seven days.

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Flumetasone

1.2 ATC Code: D07AB03 - Corticosteroids, plain; corticosteroids, moderately potent (group II)

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	I					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
HU	Not authorised					
IE	Not authorised					
MK	Not authorised					
PL	Not authorised					
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Fluocortin

1.2 ATC Code: D07AB04 - Corticosteroids, plain; corticosteroids, moderately potent (group II)

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	POM					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
MK	Not authorised					
PL	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Fluperolone

1.2 ATC Code: D07AB05 - Corticosteroids, plain; corticosteroids, moderately potent (group II)

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
MK	Not authorised					
PL	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Fluorometholone

1.2 ATC Code: D07AB06 - Corticosteroids, plain; corticosteroids, moderately potent (group II)

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
MK	Not authorised					
PL	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Fluprednidene

1.2 ATC Code: D07AB07 - Corticosteroids, plain; corticosteroids, moderately potent (group II)

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
HU	Not authorised					
IE	Not authorised					
MK	Not authorised					
PL	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Desonide

1.2 ATC Code: D07AB08 - Corticosteroids, plain; corticosteroids, moderately potent (group II)

1.3 Therapeutic indications: treatment of eczema and dermatitis including atopic eczema, photodermatitis, primary irritant and allergic dermatitis (including napkin rash), intertrigo, prurigo nodularis, seborrhoeic dermatitis (except seborrhoeic dermatitis on the face) and insect bite reactions. Treatment of psoriasis (excluding widespread plaque psoriasis).

1.4 Posology and duration of treatment: for topical application. *Dosage*: to be applied no more than twice daily.

1.5 Pharmaceutical forms: cream

1.6 Contraindications: hypersensitivity to desonide; in the presence of untreated viral or fungal infections, tubercular or syphilitic lesions, acne vulgaris and rosacea and in bacterial infections unless used in connection with appropriate chemotherapy.

1.7 Relevant warnings: as with all corticosteroids, application to the face, flexures and other areas of thin skin may cause skin atrophy and increased absorption and should be avoided. Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses following development of tolerance, risk of generalised pustular psoriasis and local and systemic toxicity due to impaired barrier function of the skin. Steroids may have a place in psoriasis of the scalp and chronic plaque psoriasis of the hands and feet. Careful patient supervision is important. Contact with the eyes should be avoided.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance):

Adverse reactions:

Immune system disorders: hypersensitivity;

Endocrine disorders: adrenal suppression;

Skin and subcutaneous tissue disorders: skin atrophy, often irreversible, with thinning of the epidermis, telangiectasia, skin striae, pustular acne, perioral dermatitis, rebound effect, skin depigmentation, dermatitis and eczema, including contact dermatitis.

2.1 Direct risks (Pharmacovigilance): -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	I					
HR	Not authorised					

IE	Not authorised					
IT	II					
PL	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I

Criteria:
Therapeutic indications
Safety profile
Medical supervision required

3.2 Paediatric use: the use in infants should be avoided.

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Triamcinolone

1.2 ATC Code: D07AB09 - Corticosteroids, plain; corticosteroids, moderately potent (group II)

1.3 Therapeutic indications: relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses.

1.4 Posology and duration of treatment: it is generally applied to the affected area as a thin film from two to four times daily depending on the severity of the condition.

1.5 Pharmaceutical forms: cream

1.6 Contraindications: hypersensitivity to triamcinolone. In the presence of untreated viral or fungal infections, tubercular or syphilitic lesions, acne vulgaris and rosacea and in bacterial infections unless used in connection with appropriate chemotherapy.

1.7 Relevant warnings: systemic absorption of topical corticosteroids has produced reversible HPA axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients. Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings. Therefore, patients receiving a large dose of a potent topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and adrenocorticotropic hormone (ACTH) stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid. Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.
Paediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.
HPA axis suppression, Cushing's syndrome and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilloedema.
Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.
If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted. In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favourable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): adverse reactions: the following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, miliaria.

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I					
AT	I					
BE	OTC, see Annex III					
BG	II					
CH	II					
CZ	I					
DE	II					
ES	Not authorised					
FI	Not authorised					
FR	Not authorised					
IE	II					
IT	II					
LT	II					
LV	I					
NL	Not authorised					
NO	II					
RO	I					
SI	II					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I

Criteria:
Therapeutic indications
Safety profile

3.2 Paediatric use: use with caution

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Alclometasone

1.2 ATC Code: D07AB10 - Corticosteroids, plain; corticosteroids, moderately potent (group II)

1.3 Therapeutic indications: for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. Alclometasone cream/ointment may be used in paediatric patients 1 year of age or older, no longer than 3 weeks. Since the safety and efficacy of alclometasone cream/ointment have not been established in paediatric patients below 1 year of age, their use in this age-group is not recommended.

1.4 Posology and duration of treatment: apply a thin film of alclometasone cream/ointment to the affected skin areas 2 or 3 times daily; massage gently until the medication disappears. Alclometasone cream/ointment may be used in paediatric patients 1 year of age or older. Safety and effectiveness of alclometasone cream/ointment in paediatric patients for more than 3 weeks of use have not been established. Use in paediatric patients under 1 year of age is not recommended. As with other corticosteroids, therapy should be discontinued when control is achieved. If no improvement is seen within 2 weeks, reassessment of diagnosis may be necessary. Alclometasone cream/ointment should not be used with occlusive dressings unless directed by a physician. Alclometasone cream/ointment should not be applied in the diaper area if the child still requires napkins as they may constitute occlusive dressing. Geriatric Use: in studies where geriatric patients (65 years of age or older) have been treated with alclometasone cream/ointment, safety did not differ from that in younger patients; therefore, no dosage adjustment is recommended.

1.5 Pharmaceutical forms: cream/ointment

1.6 Contraindications: hypersensitivity to alclometasone. In the presence of untreated viral or fungal infections, tubercular or syphilitic lesions, acne vulgaris and rosacea and in bacterial infections unless used in connection with appropriate chemotherapy.

1.7 Relevant warnings: systemic absorption of topical corticosteroids can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing syndrome, hyperglycaemia, and glycosuria can also be produced in some patients by systemic absorption of topical corticosteroids while under treatment. Patients applying a topical steroid to a large surface area or to areas under occlusion should be evaluated periodically for evidence of HPA axis suppression. The effects of alclometasone cream/ointment on the HPA axis have been evaluated. In one study, alclometasone cream/ointment were applied to 30% of the body twice daily for 7 days, and occlusive dressings were used in selected patients either 12 hours or 24 hours daily. In another study, alclometasone cream was applied to 80% of the body surface of normal subjects twice daily for 21 days with daily 12-hour periods of whole body occlusion. Average plasma and urinary free cortisol levels and urinary levels of 17-hydroxysteroids were decreased (about 10%), suggesting suppression of the HPA axis under these conditions. Plasma cortisol levels have also been demonstrated to decrease in paediatric patients treated twice daily for 3 weeks without occlusion. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent corticosteroid. Recovery of HPA axis function is generally prompt upon discontinuation of topical corticosteroids. Infrequently, signs and symptoms of glucocorticosteroid insufficiency may occur, requiring supplemental systemic corticosteroids. For information on systemic supplementation, see prescribing information for those products. Paediatric use: because of a higher ratio of skin surface area to body mass, paediatric patients are at a greater risk than adults of HPA axis suppression and Cushing syndrome when they are treated with topical corticosteroids. They are therefore also at greater risk of adrenal insufficiency during and/or after withdrawal of treatment. Adverse effects, including striae, have been reported with inappropriate use of topical corticosteroids in infants and children. Paediatric patients applying alclometasone cream/ointment to >20% of the body surface area are at higher risk for HPA axis suppression. HPA axis suppression, Cushing syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in paediatric patients receiving topical corticosteroids. Manifestations of adrenal suppression in paediatric patients include low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema. Alclometasone cream/ointment should not be used in the treatment of napkin dermatitis. If irritation develops, alclometasone cream/ointment should be discontinued and

appropriate therapy instituted. Allergic contact dermatitis with corticosteroids is usually diagnosed by observing a failure to heal rather than noting a clinical exacerbation, as with most topical products not containing corticosteroids. If concomitant skin infections are present or develop, an appropriate antifungal or antibacterial agent should be used. If a favourable response does not occur promptly, use of alclometasone cream/ointment should be discontinued until the infection has been adequately controlled.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): adverse reactions: the following local adverse reactions have been reported with alclometasone cream in approximately 2% of patients: itching and burning, erythema, dryness, irritation, and papular rashes. The following local adverse reactions have been reported with alclometasone ointment in approximately 1% of patients: itching, burning, and erythema. The following additional local adverse reactions have been reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings: folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, skin atrophy, striae, and miliaria.

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I					
AT	Not authorised					
BE	Not authorised					
CZ	I					
DE	II					
DK	II					
ES	Not authorised					
FR	Not authorised					
HR	I		Psoriasis; chronic dermatosis			
IE	II					
IT	II					
MK	I					
PL	I		Not for children < 1 year	0.05%		10 g
SI	II					
UK	II + exemption Annex III		For the short-term treatment and control of patches of eczema and dermatitis including atopic eczema and primary irritant and allergic dermatitis in adults and children 12 years and over	0.05%		

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I

Criteria:
Therapeutic indications

Safety profile

3.2 Paediatric use: use in paediatric patients under 1 year of age is not recommended.

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Hydrocortisone buteprate

1.2 ATC Code: D07AB11 - Corticosteroids, plain; corticosteroids, moderately potent (group II)

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
MK	Not authorised					
PL	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Dexamethasone

1.2 ATC Code: D07AB19 - Corticosteroids, plain; corticosteroids, moderately potent (group II)

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
MK	Not authorised					
PL	POM		Not to be used in vaccination reaction sites; not to be used in case of hypersensitivity, viral/bacterial/fungal skin diseases, cancer and precancerous lesions of the skin, acne or rosacea, dermatitis around the mouth	0.028%		32.5%

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Clocortolone

1.2 ATC Code: D07AB21 - Corticosteroids, plain; corticosteroids, moderately potent (group II)

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
MK	Not authorised					
PL	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Combinations of corticosteroids

1.2 ATC Code: D07AB30 - Corticosteroids, plain; corticosteroids, moderately potent (group II)

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
MK	Not authorised					
PL	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Betamethasone

1.2 ATC Code: D07AC01 - Corticosteroids, plain; corticosteroids, potent (group III)

1.3 Therapeutic indications: *cream/ointment:* treatment of eczema and dermatitis of all types, including atopic eczema, photodermatitis, lichen planus, lichen simplex, prurigo nodularis, discoid lupus erythematosus, necrobiosis lipoidica, pretibial myxoedema and erythroderma. It is also effective in the less responsive conditions such as psoriasis of the scalp and chronic plaque psoriasis of the hands and feet, but excluding widespread plaque psoriasis. *Lotion:* treatment of eczema and dermatitis of all types effecting the scalp including atopic eczema, photodermatitis, primary irritant and allergic dermatitis, lichen planus, lichen simplex, discoid lupus erythematosus, erythroderma. It is also indicated for psoriasis of the scalp.

1.4 Posology and duration of treatment: once to twice daily. In most cases a thin film of cream/ointment should be applied to cover the affected area twice daily. For some patients adequate maintenance therapy may be achieved with less frequent application. Cream is especially appropriate for moist or weeping surfaces and the ointment for dry, lichenified or scaly lesions but this is not invariably so.

1.5 Pharmaceutical forms: cream/ointment/lotion

1.6 Contraindications: rosacea, acne, perioral dermatitis, perianal and genital pruritus; hypersensitivity to betamethasone; tuberculous and most viral lesions of the skin, particularly herpes simplex, vaccinia, varicella; in napkin eruptions, fungal or bacterial skin infections without suitable concomitant anti-infective therapy.

1.7 Relevant warnings: local and systemic toxicity is common, especially following long continuous use on large areas of damaged skin, in flexures or with polythene occlusion. If used in children or on the face, courses should be limited to 5 days. Long term continuous therapy should be avoided in all patients irrespective of age. Occlusion must not be used. Topical corticosteroids may be hazardous in psoriasis for a number of reasons, including rebound relapses following development of tolerance, risk of generalised pustular psoriasis and local systemic toxicity due to impaired barrier function of the skin. Careful patient supervision is important.

General: systemic absorption of topical corticosteroids can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome also can be produced in some patients by systemic absorption of topical corticosteroids while on treatment. Patients receiving a large dose of a potent topical steroid applied to a large surface area should be evaluated periodically for evidence of HPA axis suppression: if noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent corticosteroid. Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids. Paediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios. If irritation develops, treatment should be discontinued and appropriate therapy instituted.

Paediatric use: paediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and to exogenous corticosteroid-induced HPA axis suppression and to exogenous corticosteroid effects than adult patients because of greater absorption due to a larger skin surface area to body weight ratio. HPA axis suppression, Cushing's syndrome and intracranial hypertension have been reported in paediatric patients receiving topical corticosteroids. Manifestations of adrenal suppression in paediatric patients include linear growth retardation, delayed weight gain, low plasma cortisol levels and an absence of response to ACTH stimulation. Manifestations of intracranial hypertension include a bulging fontanelle, headaches and bilateral papilloedema.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): adverse reaction: Cutaneous use of betamethasone is generally well tolerated and side-effects are rare. The systemic absorption of betamethasone may be increased if extensive body surface areas or skin folds are treated for prolonged periods or with excessive

amounts of steroids. Suitable precautions should be taken in these circumstances, particularly with infants and children. The following local adverse reactions that have been reported with the use of betamethasone include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, striae and miliaria. Continuous application without interruption may result in local atrophy of the skin, striae and superficial vascular dilation, particularly on the face.

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I					
AT	Not authorised					
BE	I					
CZ	I					
ES	POM					
FR	I					
HR	I					
IE	II					
IT	II	Cutaneous	Relief of the inflammatory and pruritic manifestations of steroid responsive dermatoses Warning: not for long-term use, unless indicated by a doctor	0.05%		
MK	I	Cutaneous	Skin diseases responsive to local therapy with corticosteroids	0.05%		20 g
PL	I	Cutaneous		0.05%		20 g
RO	I					
SI	I					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I

Criteria:
Therapeutic indications
Safety profile
Medical supervision

3.2 Paediatric use: use with caution, short treatments only.

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Fluclorolone

1.2 ATC Code: D07AC02 - Corticosteroids, plain; corticosteroids, potent (group III)

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	POM					
HR	Not authorised					
IE	Not authorised					
MK	Not authorised					
PL	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Desoximetasone

1.2 ATC Code: D07AC03 - Corticosteroids, plain; corticosteroids, potent (group III)

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
IT	II	Cutaneous		2.5 mg		37.5 mg
PL	Not authorised					
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Fluocinolone acetonide

1.2 ATC Code: D07AC04 - Corticosteroids, plain; corticosteroids, potent (group III)

1.3 Therapeutic indications: treatment of skin lesions as in atopic dermatitis, neurodermatitis, contact dermatitis, seborrheic dermatitis, anogenital pruritus, lichen simplex chronicus, stasis dermatitis, intertrigo, exfoliative dermatitis, psoriasis (chronic stage, stabilised).

1.4 Posology and duration of treatment: the ointment is applied in a thin layer on the affected skin, 2 - 3 times daily gently massage the area after application. Duration of the treatment should not exceed 2 - 3 weeks.

1.5 Pharmaceutical forms: ointment

1.6 Contraindications: rosacea, acne, perioral dermatitis, perianal and genital pruritus; hypersensitivity to fluocinolone acetonide; tuberculous and most viral lesions of the skin, particularly herpes simplex, vaccinia, varicella; in fungal or bacterial skin infections without suitable concomitant anti-infective therapy.

1.7 Relevant warnings: local and systemic toxicity is common, especially following long continuous use on large areas of damaged skin, in flexures or with polythene occlusion. If used in children or on the face, courses should be limited to 5 days. Long term continuous therapy should be avoided in all patients irrespective of age. If irritation develops, treatment should be discontinued and appropriate therapy instituted.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): adverse reactions: The systemic absorption of fluocinolone acetonide may be increased if extensive body surface areas or skin folds are treated for prolonged periods or with excessive amounts of steroids. Suitable precautions should be taken in these circumstances, particularly with infants and children. The following local adverse reactions that have been reported with the use of fluocinolone acetonide include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, striae and miliaria. Continuous application without interruption may result in local atrophy of the skin, striae and superficial vascular dilation, particularly on the face.

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I					
AT	Not authorised					
BE	Not authorised					
CZ	I					
ES	POM					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					

IT	I + exemption Annex III	Cutaneous		0.025%		30 g
MK	I	Cutaneous	Relief of inflammatory and pruritic manifestations of corticosteroids-responsive manifestations	0.025%		15 g
PL	I	Cutaneous	Uncomplicated skin inflammatory infections with persistent itching or hyperkeratosis, responsive to glucocorticoids Available pharmaceutical forms: gel, ointment; Do not use in children < 2 years	0.025%		15 g
SI	I					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I

Criteria:
Therapeutic indications
Safety profile
Medical supervision

3.2 Paediatric use: courses should be limited to 5 days.

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Fluocortolone

1.2 ATC Code: D07AC05 - Corticosteroids, plain; corticosteroids, potent (group III)

1.3 Therapeutic indications: all corticosteroid-responsive dermatoses such as a local: contact dermatitis, eczema vulgar, nummular, degenerative and seborrheic dermatitis, dyshidrotic eczema, eczema in varicose symptom complex (but not directly on ulcers of the lower extremities), eczema in children, atopic dermatitis, psoriasis, lichen planus verrucosus, chronic discoid lupus erythematosus, insect bites.

1.4 Posology and duration of treatment: at the start of the treatment, the ointment is applied thinly 2 - 3 times daily. Once the disease has been improved, one application per day is often sufficient. Infants, children and adults should not be treated for more than 3 weeks. Glucocorticoids are used only for so long, and applied only in such low doses as to achieve and maintain the desired therapeutic action. In severe cases, a persistent occlusive dressing may be appropriate. The dressing should generally not remain in place for more than 24 hours. When developing an infection, occlusive treatment should be discontinued.

1.5 Pharmaceutical forms: cream/ointment

1.6 Contraindications: rosacea, acne, perioral dermatitis, perianal and genital pruritus; hypersensitivity to fluocortolone; tuberculous and most viral lesions of the skin, particularly herpes simplex, vaccinia, varicella; in fungal or bacterial skin infections without suitable concomitant anti-infective therapy.

1.7 Relevant warnings: local and systemic toxicity is common, especially following long continuous use on large areas of damaged skin, in flexures or with occlusion. If used in children or on the face, courses should be limited to 5 days. Long term continuous therapy should be avoided in all patients irrespective of age. Topical steroids may be hazardous in psoriasis for a number of reasons including rebound relapses following development of tolerance, risk of centralised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin. If used in psoriasis careful patient supervision is important. If irritation develops, treatment should be discontinued and appropriate therapy instituted. Should an infection develop, use of an appropriate antifungal or antibacterial agent should be instituted. If a favourable response does not occur promptly, the corticosteroid should be discontinued until the infection is adequately controlled.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): adverse reactions: local symptoms such as itching, burning, erythema or vesicle formation can occur during treatment with ointment in individual cases. Following topical application on a large area (about 10% of the body surface or more) or long-term use (more than 4 weeks) of corticosteroids, local symptoms such as skin atrophy, telangiectasia, striae, acneiform skin changes and systemic effects of corticosteroid may occur. As with other corticosteroids for topical use, adverse events can occur in rare cases: folliculitis, hypertrichosis, perioral dermatitis, hypopigmentation, allergic skin reaction.

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	POM					
FR	I					
HR	Not authorised					
IE	Not authorised					
IT	II					
MK	Not authorised					
PL	Not authorised					
RO	I					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I

Criteria:
Therapeutic indications
Safety profile
Medical supervision

3.2 Paediatric use: short courses of treatment.

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Diflucortolone

1.2 ATC Code: D07AC06 - Corticosteroids, plain; corticosteroids, potent (group III)

1.3 Therapeutic indications: for the topical treatment of corticoid-responsive dermatoses that are unresponsive to less potent corticosteroids and in the absence of infection.

1.4 Posology and duration of treatment: *Adults*: initially, diflucortolone should be applied thinly twice daily. When the condition improves or when longer periods of treatment are required one application daily is appropriate.
Long-term continuous therapy with topical corticosteroids should be avoided, with a usual maximum duration of 4 weeks. If used on the face, courses should be limited to 5 days and occlusion should not be used.
Children 1-4 years of age: diflucortolone should be applied thinly twice daily. It should be used with great care, for short periods and generally only on the advice of a doctor specialising in dermatology. Courses should be limited to 5 days and occlusion should not be used.
Children 5 years of age and over: initially, diflucortolone should be applied thinly twice daily. When the condition improves one application daily is appropriate. Courses should be limited to 1–2 weeks. If used on the face, courses should be limited to 5 days and occlusion should not be used.
Infants: diflucortolone should not be used in children under 1 year of age.

1.5 Pharmaceutical forms: cream/ointment

1.6 Contraindications: rosacea and peri-oral dermatitis; acne vulgaris, undiagnosed perianal and genital pruritus, napkin eruptions, viral infections, primary bacterial or fungal infections of the skin; secondary infections in the absence of appropriate anti-infective therapy; post vaccination skin reactions in the area to be treated; not suitable for the treatment of ophthalmic conditions; hypersensitivity to the active substances or to any of the excipients.

1.7 Relevant warnings: long-term continuous therapy with topical corticosteroids should be avoided, with a usual maximum duration of 4 weeks irrespective of age. Adrenal suppression can occur, even without occlusion. If used on children up to the age of 4 years or on the face, courses should be limited to 5 days and occlusion should not be used.
Difluocortolone may be applied under an occlusive dressing. However, each dressing should not be left on for more than 24 hours. Although occlusive dressings may be used repeatedly, it should be noted that systemic corticoid absorption is likely to be increased with a consequent increased risk of adrenal suppression. If occlusive treatment is expected to be prolonged, it is advisable to change the dressing every 12 hours.
Difluocortolone should not be allowed to come into contact with the eyes.
Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses following development of tolerance, risk of generalised pustular psoriasis, and local and systemic toxicity due to impaired barrier function of the skin. Careful patient supervision is important in psoriasis.
Exacerbation of skin infections may occur. Infections or secondarily infected dermatoses require additional therapy with antibiotics or chemotherapeutic agents. This treatment can often be topical, but for heavy infections systemic antibacterial therapy may be necessary. If fungal infections are present, a topically active antimycotic should be applied.
If aggravation of skin irritation develops with the use of difluocortolone, treatment should be withdrawn and appropriate therapy installed.
Allergic contact dermatitis due to topical corticosteroids can occur. In these cases eczema fails to improve or deteriorates with treatment. Corticosteroid hypersensitivity occurs most frequently among patients with stasis dermatitis and leg ulceration. Such an observation should be corroborated with appropriate diagnostic patch testing.
Patients with an allergy to corticosteroids may cross-react to several corticosteroids to which they have not previously been exposed. After topical application, allergies to cross-reacting systemically applied corticosteroids may occur.
As known from systemic corticoids, glaucoma may also develop by using local corticoids (e.g. after large doses or extensive application over a prolonged period, occlusive dressing technique or application to the skin around the eyes).

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): common local adverse reactions reported with difluocortolone include burning, pruritus, erythema and irritations. In common with all other topical corticoids, side-effects may occur when difluocortolone is applied to large areas of the body (10% or more) and for long periods of time (more than four weeks), especially if the ointment or an occlusive dressing is being used. There may be local signs such as atrophy of the skin, telangiectasia, striae, acneiform changes, perioral dermatitis and hypertrichosis, or systemic corticoid effects caused by absorption. Systemic absorption can produce the features of hypercorticism. Therefore, caution should be exercised when using occlusive dressings, as there is a possibility that natural steroid production may be suppressed. In rare cases, allergic skin reactions may occur.

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I					
AT	I					
BE	I					
CZ	Not authorised					
ES	POM					
FR	I					
HR	Not authorised					
IE	Not authorised					
IT	II					
PL	Not authorised					
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I

Criteria:
Therapeutic indications
Safety profile
Medical supervision

3.2 Paediatric use: not be used in children under 1 year of age; *Children 1-4 years of age:* courses should be limited to 5 days and occlusion should not be used; *Children 5 years of age and over*: courses should be limited to 1–2 weeks. If used on the face, courses should be limited to 5 days and occlusion should not be used.

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)

PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Fludroxycortide

1.2 ATC Code: D07AC07 - Corticosteroids, plain; corticosteroids, potent (group III)

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
IT	Not authorised					
MK	Not authorised					
PL	Not authorised					
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Fluocinonide

1.2 ATC Code: D07AC08 - Corticosteroids, plain; corticosteroids, potent (group III)

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	POM					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
MK	Not authorised					
PL	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Budesonide

1.2 ATC Code: D07AC09 - Corticosteroids, plain; corticosteroids, potent (group III)

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
IT	II					
MK	Not authorised					
PL	Not authorised					
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Diflorasone

1.2 ATC Code: D07AC10 - Corticosteroids, plain; corticosteroids, potent (group III)

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	POM					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
IT	Not authorised					
MK	Not authorised					
PL	Not authorised					
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Amcinonide

1.2 ATC Code: D07AC11 - Corticosteroids, plain; corticosteroids, potent (group III)

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	I					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
IT	Not authorised					
MK	Not authorised					
PL	Not authorised					
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Halometasone

1.2 ATC Code: D07AC12 - Corticosteroids, plain; corticosteroids, potent (group III)

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
IT	Not authorised					
MK	Not authorised					
PL	Not authorised					
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Mometasone

1.2 ATC Code: D07AC13 - Corticosteroids, plain; corticosteroids, potent (group III)

1.3 Therapeutic indications: *cream/ointment:* Treatment of inflammatory and pruritic manifestations of psoriasis (excluding widespread plaque psoriasis) and atopic dermatitis.

Scalp lotion: Treatment of inflammatory and pruritic manifestations of psoriasis and seborrhoeic dermatitis of the scalp.

1.4 Posology and duration of treatment: *Cream/ointment:* adults, including elderly patients and children: a thin film of ointment/cream should be applied to the affected areas of skin once daily.

Scalp lotion: a few drops of scalp lotion should be applied to affected scalp sites, once daily; massage gently and thoroughly until the medication disappears. Use of topical corticosteroids in children or on the face should be limited to the least amount compatible with an effective therapeutic regimen and duration of treatment should be no more than 5 days.

1.5 Pharmaceutical forms: cream/ointment/scalp lotion

1.6 Contraindications: it should not be used on wounds or on skin which is ulcerated. It should not be used in patients who are sensitive to mometasone furoate.

Cream/ointment: facial rosacea, acne vulgaris, skin atrophy, perioral dermatitis, perianal and genital pruritis, napkin eruptions, bacterial (e.g. impetigo, pyodermas), viral (e.g. herpes simplex, herpes zoster and chickenpox verrucae vulgares, condylomata acuminata, molluscum contagiosum), parasitical and fungal (e.g. candida or dermatophyte) infections, varicella, tuberculosis, syphilis or post-vaccine reactions.

Scalp lotion: skin atrophy, bacterial (e.g. impetigo, pyodermas), viral (e.g. herpes simplex, herpes zoster and chickenpox, verrucae vulgares, condylomata acuminata, molluscum contagiosum) parasitical and fungal (e.g. candida or dermatophyte) infections of the scalp.

1.7 Relevant warnings: if irritation or sensitisation develops, treatment should be withdrawn and appropriate therapy instituted. Should an infection develop, use of an appropriate antifungal or antibacterial agent should be instituted. If a favourable response does not occur promptly, the corticosteroid should be discontinued until the infection is adequately controlled. Systemic absorption of topical corticosteriods can produce HPA axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycaemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment. Patients applying a topical steroid to a large surface area or areas under occlusion should be evaluated periodically for evidence of HPA axis suppression. Paediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios. Local and systemic toxicity is common especially following long continued use on large areas of damaged skin, in flexures and with polythene occlusion. If used in childhood, or on the face, occlusion should not be used. If used on the face, courses should be limited to 5 days and occlusion should not be used. Long term continuous therapy should be avoided in all patients irrespective of age. Topical steroids may be hazardous in psoriasis for a number of reasons including rebound relapses following development of tolerance, risk of centralised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin. If used in psoriasis careful patient supervision is important. As with all potent topical glucocorticoids, avoid sudden discontinuation of treatment. When long term topical treatment with potent glucocorticoids is stopped, a rebound phenomenon can develop which takes the form of a dermatitis with intense redness, stinging and burning. This can be prevented by slow reduction of the treatment, for instance, continue treatment on an intermittent basis before discontinuing. Glucocorticoids can change the appearance of some lesions and make it difficult to establish an adequate diagnosis and can also delay the healing. Topical preparations with mometasone are not for ophthalmic use, including the eyelids, because of the very rare risk of glaucoma simplex or subcapsular cataract.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance):

Adverse reactions:

Infections and infestations:
Not known: infection, furuncle;
Very rare: folliculitis.

Nervous system disorders:
Not known: paraesthesia;
Very rare: burning sensation.

Skin and subcutaneous tissue disorders:
Not known: Dermatitis contact, skin hypopigmentation, hypertrichosis, skin striae, dermatitis acneiform, skin atrophy;
Very rare: pruritus.

General disorders and administration site conditions: not known: application site pain, application site reactions

Local adverse reactions reported infrequently with topical dermatologic corticosteroids include: skin dryness, irritation, dermatitis, perioral dermatitis, maceration of the skin, miliaria and telangiectasiae. Paediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced hypothalamic-pituitary-adrenal axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio. Chronic corticosteroids therapy may interfere with the growth and development of children.

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I					
AT	I					
BE	I	Cutaneous		0.1%		100 mg
CZ	I	Cutaneous	Inflammatory skin diseases	0.1%		100 mg
DE	Not authorised					
ES	POM					
FR	Not authorised					
HR	I					
IE	II			0.1%		100 mg
IT	II					
MK	I	Cutaneous	Relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses	0.1%		150 mg
PL	I	Cutaneous	Symptomatic relief of inflammation and itching of glucocorticoid-responsive dermatoses Available pharmaceutical forms: cream, ointment, skin liquid. To be used once/day on the affected skin. Warning: do not use in children < 2 years	0.1%		20 ml
RO	Not authorised					
SI	I					
UK	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

References: List I

Criteria
Therapeutic indications
Safety profile

3.2 Paediatric use: as the safety and efficacy of mometasone in paediatric patients below 2 years of age have not been established, its use in this age group is not recommended.

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Methylprednisolone aceponate

1.2 ATC Code: D07AC14 - Corticosteroids, plain; corticosteroids, potent (group III)

1.3 Therapeutic indications: treatment of acute exogenous eczema (allergic contact dermatitis, toxic degenerative eczema, nummular eczema, dyshidrotic eczema), atopic dermatitis (neurodermatitis), seborrheic eczema, gravitational eczema, solar dermatitis (severe sunburn).

1.4 Posology and duration of treatment: it is to be used topically and applied thinly once daily to the affected areas and rubbed in lightly. In general, the duration of use should not exceed 2 weeks.

Paediatric population: dose adjustments are not required when methylprednisolone aceponate is administered to infants aged 4 months or older, children and adolescents. The safety of methylprednisolone aceponate in infants below the age of 4 months has not been established. No data are available.

1.5 Pharmaceutical forms: cream/ointment/cutaneous emulsion

1.6 Contraindications: tuberculous or syphilitic processes in the area to be treated; virus diseases (e.g. varicella, herpes zoster), rosacea, perioral dermatitis, ulcers, acne vulgaris, atrophic skin diseases and postvaccination skin reactions in the area to be treated. Hypersensitivity to methylprednisolone aceponate.

1.7 Relevant warnings: local skin infections can be potentiated by topical glucocorticoid use. Additional, specific therapy is required in bacterially infected skin diseases and/or in fungal infections. Care must be taken when using methylprednisolone aceponate cream/ointment/cutaneous emulsion to avoid contact with the eyes, deep open wounds and mucosae. No impairment of the adrenocortical function has been observed in children on large-area (40-90 % of the skin surface) non-occlusive treatment with methylprednisolone aceponate 0.1% ointment. After application of methylprednisolone aceponate 0.1% ointment to 60 % skin surface area under occlusive conditions for 22 hours, suppression of plasma cortisol levels and influence on circadian rhythm was observed in adult healthy volunteers. Therefore, methylprednisolone aceponate should not be used under occlusive conditions. Nappies can be occlusive. This is especially relevant as methylprednisolone aceponate is not recommended for use in babies under the age of 4 months. As known from systemic corticoids, glaucoma may also develop from using local corticoids (e.g. after large-dosed or extensive application over a prolonged period, occlusive dressing techniques, or application to the skin around the eyes).

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance):

Adverse reactions:

General disorders and administration site reaction
Common: application site burning;
Uncommon: application site pain, application site vesicles, application site pruritus, application site pustules, application site erosion.

Skin and subcutaneous tissue disorders: Uncommon: eczema, skin exfoliation, skin fissures.

As with other corticoids for topical application, the following local side effects may occur: skin atrophy, application site dryness and application site erythema, skin striae, application site folliculitis, hypertrichosis, telangiectasia, perioral dermatitis, skin discoloration, acne, and/or allergic skin reactions to any of the ingredients of the formulation. Systemic effects due to absorption may occur when topical preparations containing corticoids are applied.

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I					
AT	I					
BE	I	Cutaneous		0.1%		15 mg
CZ	I	Cutaneous		0.1%		100 mg
ES	POM					
FR	Not authorised					
HR	I	Cutaneous		0.1%		15 mg
IE	Not authorised					
IT	II					
PL	I	Cutaneous	Eczema; contact dermatitis Available pharmaceutical forms: emulsion, cream, ointment. Posology: apply once/day. Warning: children > 2 years: use no longer than 2 weeks; adults: use no longer than 12 weeks	0.1%		15 mg
RO	Not authorised					
SI	I					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I

Criteria:
Therapeutic indications
Safety profile
Medical supervision

3.2 Paediatric use: not recommended for use in babies under the age of 4 months as the safety has not been established for this age group.

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Beclometasone

1.2 ATC Code: D07AC15 - Corticosteroids, plain; corticosteroids, potent (group III)

1.3 Therapeutic indications: treatment of allergic contact dermatitis, dyshidrotic eczema, atopic dermatitis (neurodermatitis), seborrheic eczema.

1.4 Posology and duration of treatment: adults and children >5 years: it is to be used topically and applied thinly once – twice daily to the affected areas. In general, the duration of use should not exceed 2 weeks.

1.5 Pharmaceutical forms: cream/ointment/cutaneous emulsion

1.6 Contraindications: tuberculous or syphilitic processes in the area to be treated; virus diseases (e.g. varicella, herpes zoster), rosacea, perioral dermatitis, ulcers, acne vulgaris, atrophic skin diseases and post-vaccination skin reactions in the area to be treated; hypersensitivity to beclometasone.

1.7 Relevant warnings: local skin infections can be potentiated by topical glucocorticoid use. Additional, specific therapy is required in bacterially infected skin diseases and/or in fungal infections. Care must be taken when using beclometasone cream/ointment/cutaneous emulsion to avoid contact with the eyes, deep open wounds and mucosae. As known from systemic corticoids, glaucoma may also develop from using local corticoids (e.g. after large-dosed or extensive application over a prolonged period, occlusive dressing techniques, or application to the skin around the eyes).

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance):

General disorders and administration site reaction
Application site burning, application site pain, application site vesicles, application site pruritus, application site pustules, application site erosion;

Skin and subcutaneous tissue disorders: eczema, skin exfoliation, skin fissures.

As with other corticoids for topical application, the following local side effects may occur: skin atrophy, application site dryness and application site erythema, skin striae, application site folliculitis, hypertrichosis, telangiectasia, perioral dermatitis, skin discoloration, acne, and/or allergic skin reactions to any of the ingredients of the formulation. Systemic effects due to absorption may occur when topical preparations containing corticoids are applied.

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	POM					
FR	Not authorised					

HR	Not authorised					
IE	Not authorised					
IT	II					
MK	Not authorised					
PL	Not authorised					
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I (1)

Criteria:
Therapeutic indications
Safety profile
Medical supervision needed

3.2 Paediatric use: not to be used in children < 5 years (lack of efficacy and safety data).

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Hydrocortisone aceponate

1.2 ATC Code: D07AC16 - Corticosteroids, plain; corticosteroids, potent (group III)

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	POM					
FR	I					
HR	Not authorised					
IE	Not authorised					
IT	Not authorised					
MK	Not authorised					
PL	Not authorised					
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Fluticasone

1.2 ATC Code: D07AC17 - Corticosteroids, plain; corticosteroids, potent (group III)

1.3 Therapeutic indications: treatment of inflammatory dermatoses.
Adults: fluticasone propionate cream/ointment is a potent topical corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses; these include the following: topic dermatitis; nummular dermatitis (discoid eczemas); prurigo nodularis; psoriasis (excluding widespread plaque psoriasis); lichen simplex chronicus (neurodermatitis) and lichen planus; seborrhoeic dermatitis; irritant or allergic contact dermatitis; discoid lupus erythematosus; an adjunct to systemic steroid therapy in generalised erythroderma; insect bite reactions; miliaria (prickly heat).
Children: for children and infants aged three months and over who are unresponsive to lower potency corticosteroids, fluticasone is indicated for the relief of the inflammatory and pruritic manifestations of atopic dermatitis under the supervision of a specialist. Expert opinion should be sought prior to the use of fluticasone cream/ointment in other corticosteroid-responsive dermatoses in children.

1.4 Posology and duration of treatment: adults, elderly, children and infants aged 3 months and over: creams are especially appropriate for moist or weeping surfaces. Ointments are especially appropriate for dry, lichenified or scaly lesions. Apply thinly and gently rub in using only enough to cover the entire affected area once or twice a day for up to 4 weeks until improvement occurs, then reduce the frequency of application or change the treatment to a less potent preparation. Allow adequate time for absorption after each application before applying an emollient. Therapy with topical corticosteroids should be gradually discontinued once control is achieved and an emollient continued as maintenance therapy. Rebound of pre-existing dermatoses can occur with abrupt discontinuation of topical steroids especially with potent preparations.

Duration of treatment for adults and elderly: if the condition worsens or does not improve within four weeks, treatment and diagnosis should be re-evaluated.

Children over 3 months: children are more likely to develop local and systemic side effects of topical corticosteroids and, in general, require shorter courses and less potent agents than adults. Care should be taken when using fluticasone propionate to ensure the amount applied is the minimum that provides therapeutic benefit.

Duration of treatment for children and Infants: when fluticasone is used in the treatment of children, if there is no improvement within 7 – 14 days, treatment should be withdrawn and the child re-evaluated. Once the condition has been controlled (usually within 7–14 days), frequency of application should be reduced to the lowest effective dose for the shortest possible time. Continuous daily treatment for longer than 4 weeks is not recommended.

1.5 Pharmaceutical forms: cream/ointment

1.6 Contraindications: hypersensitivity to the fluticasone. The following conditions should not be treated with fluticasone: untreated cutaneous infections; rosacea; acne vulgaris; perioral dermatitis; perianal and genital pruritus; pruritus without inflammation; dermatoses in infants under three months of age, including dermatitis and nappy rash.

1.7 Relevant warnings: fluticasone propionate should be used with caution in patients with a history of local hypersensitivity to other corticosteroids. Local hypersensitivity reactions may resemble symptoms of the condition under treatment. Manifestations of hypercortisolism (Cushing's syndrome) and reversible HPA axis suppression, leading to glucocorticosteroid insufficiency, can occur in some individuals as a result of increased systemic absorption of topical steroids. If either of the above are observed, withdraw the drug gradually by reducing the frequency of application, or by substituting a less potent corticosteroid. Abrupt withdrawal of treatment may result in glucocorticosteroid insufficiency. In infants and children under 12 years of age, long-term continuous topical corticosteroid therapy should be avoided where possible, as adrenal suppression is more likely to occur. Topical steroids should be used with caution in psoriasis as rebound relapses, development of tolerance, risk of generalised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin have been reported in some cases. If used in psoriasis, careful patient supervision is important.
Prolonged application to the face is undesirable as this area is more susceptible to atrophic changes. If

applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as cataract and glaucoma might result from repeated exposure. Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions which have become infected. Any spread of infection requires withdrawal of topical corticosteroid therapy and administration of appropriate antimicrobial therapy. Bacterial infection is encouraged by the warm, moist conditions within skin folds or caused by occlusive dressings. When using occlusive dressings, the skin should be cleansed before a fresh dressing is applied. Topical corticosteroids are sometimes used to treat the dermatitis around chronic leg ulcers. However, this use may be associated with a higher occurrence of local hypersensitivity reactions and an increased risk of local infection.

Cream/ointment: overt suppression of the HPA-axis (morning plasma cortisol less than 5 micrograms/dl) is very unlikely to result from therapeutic use of fluticasone propionate cream or ointment unless treating more than 50% of an adult's body surface and applying more than 20 g per day.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance):

Adverse effects:

Infections and infestations: very rare: opportunistic infection;

Immune system disorders: very rare: hypersensitivity.

Endocrine disorders: Very rare: HPA axis suppression.

Skin and subcutaneous tissue disorders:
Common: pruritus
Uncommon: local skin burning
Very rare: skin thinning, atrophy, striae, telangiectasias, pigmentation changes hypertrichosis, allergic contact dermatitis, exacerbation of underlying symptoms, pustular psoriasis, erythema, rash, urticaria.

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I (1)					
AT	I					
BE	I	Cutaneous		0.05%		15 mg
CZ	I	Cutaneous	Inflammatory skin diseases	0.05%		7.5 mg
ES	POM					
FR	I					
HR	Not authorised					
IE	Not authorised					
IT	II					
MK	Not authorised					
PL	I	Cutaneous	Treatment of inflammation and itchy skin diseases responsive to treatment with corticosteroids Available pharmaceutical forms: cream, ointment. Warning; do not use in children < 1 year with inflammatory skin and diaper dermatitis	0.05%		15 g
SI	I					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I (1)

Criteria:
Therapeutic indications
Safety profile
Medical supervision

3.2 Paediatric use: duration of treatment for children and infants: when fluticasone is used in the treatment of children, if there is no improvement within 7 – 14 days, treatment should be withdrawn and the child re-evaluated. Once the condition has been controlled (usually within 7–14 days), frequency of application should be reduced to the lowest effective dose for the shortest possible time. Continuous daily treatment for longer than 4 weeks is not recommended.

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Prednicarbate

1.2 ATC Code: D07AC18 - Corticosteroids, plain; corticosteroids, potent (group III)

1.3 Therapeutic indications: treatment of inflammatory skin disorders, such as moderate eczema.

1.4 Posology and duration of treatment: the cream should be applied once per day in a thin layer to the affected area of the skin and gently rub. If necessary, the frequency of application can be increased to twice daily. The course of treatment should be limited at two weeks.

1.5 Pharmaceutical forms: cream

1.6 Contraindications: hypersensitivity to prednicarbate; use in the eye; bacterial skin manifestations such as tuberculosis, syphilis or viral skin manifestations such as chickenpox or oral herpes infection; rosacea; perioral dermatitis.

1.7 Relevant warnings: repeated or prolonged treatment areas near the eyes require medical supervision. Avoid contact with the eyes, as repeated penetration of even small amounts of prednicarbate in the conjunctival sac can lead to an increase in intraocular pressure.
Prednicarbate should be used in conjunction with appropriate antibacterial or antifungal treatment for the symptomatic treatment of local bacterial and/or mycotic infections of the skin.
Due to possible systemic effects caused by absorption of glucocorticoids, prednicarbate can be used in infants only when absolutely necessary, and the treatment should be limited to the minimum effective dose.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): less common side effects: or irritation of the skin. Rarely occurs: pruritus, folliculitis or allergic skin reactions. Other side effects that can occur include skin atrophy, telangiectasia, purpura and stretch marks on the skin (striae distensae), perioral rosacea with and without skin atrophy; rebound effect and delayed wound healing. When applied to the eye, there is an increased risk of glaucoma and/or cataracts. Due to the immunosuppressive effects of glucocorticoids, skin infections such as fungal, bacterial or viral infections (e.g., herpes simplex) can be masked or worsen. Depigmentation and localised or generalised increased hairiness (hypertrichosis) can be observed. Risk of local side effects increases with longer duration treatment and / or the use of occlusive bandage, or in particularly sensitive areas of the skin, for example, the face.

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
MeIclass database*	I					
AT	Not authorised					
BE	Not authorised					
CZ	I	Cutaneous	Inflammatory skin diseases, e.g. eczema, lichen planus	0.05%		7.5 mg
ES	POM					
FR	Not authorised					

HR	I	Cutaneous				100 mg
IE	Not authorised					
IT	II					
PL	Not authorised					
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I (1)

Criteria:
Therapeutic indication
Safety profile
Medical supervisions

3.2 Paediatric use: due to possible systemic effects caused by absorption of glucocorticoids, prednicarbate can be used in infants only when absolutely necessary, and the treatment should be limited to the minimum effective dose.

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Difluprednate

1.2 ATC Code: D07AC19 - Corticosteroids, plain; corticosteroids, potent (group III)

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	I		Psoriasis, dermatitis, eczema, lichen, pruritus Warning: do not use on large skin surfaces, do not use for long period of treatment			
HR	Not authorised					
IE	Not authorised					
IT	Not authorised					
MK	Not authorised					
PL	Not authorised					
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Ulobetasol

1.2 ATC Code: D07AC21 - Corticosteroids, plain; corticosteroids, potent (group III)

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
IT	Not authorised					
MK	Not authorised					
PL	Not authorised					
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Clobetasol

1.2 ATC Code: D07AD01 - Corticosteroids, plain; corticosteroids, very potent (group IV)

1.3 Therapeutic indications: *cream/ointment:* used in short courses for the treatment of more resistant dermatoses such as psoriasis (excluding widespread plaque psoriasis), recalcitrant eczemas, lichen planus, discoid lupus erythematosus, and other skin conditions which do not respond satisfactorily to less active steroids.

Scalp lotion: used in short courses for the treatment of psoriasis and recalcitrant eczemas of the scalp.

1.4 Posology and duration of treatment: *cream/ointment/scalp lotion:* apply sparingly to the affected area once or twice daily until improvement occurs. As with other highly active topical steroid preparations, therapy should be discontinued when control is achieved. In the more responsive conditions this may be within a few days. If no improvement is seen within 2 - 4 weeks, reassessment of the diagnosis, or referral, may be necessary. Repeated short courses of clobetasol may be used to control exacerbations. If continuous steroid treatment is necessary, a less potent preparation should be used.
Cream/ointment: in very resistant lesions, especially where there is hyperkeratosis, the anti-inflammatory effect of clobetasol can be enhanced, if necessary, by occluding the treatment area. Overnight occlusion only is usually adequate to bring about a satisfactory response. Thereafter improvement can usually be maintained by application without occlusion.

1.5 Pharmaceutical forms: cream/ointment/scalp lotion

1.6 Contraindications: *cream/ointment:* rosacea, acne vulgaris, perioral dermatitis, perianal and genital pruritus, primary cutaneous viral infections (e.g. herpes simplex, chickenpox), hypersensitivity to clobetasol. In the treatment of primary infected skin lesions caused by infection with fungi (e.g. candidiasis, tinea) or bacteria (e.g. impetigo); or dermatoses in children under one year of age, including dermatitis and napkin eruptions.
Scalp lotion: infections of the scalp; hypersensitivity to clobetasol; dermatoses in children under one year of age, including dermatitis.

1.7 Relevant warnings: long-term continuous therapy should be avoided where possible, particularly in infants and children, as adrenal suppression can occur even without occlusion. If clobetasol is required for use in children, it is recommended that the treatment should be reviewed weekly. It should be noted that the infant's napkin may act as an occlusive dressing. If used in childhood or on the face, courses should be limited if possible to 5 days and occlusion should not be used. The face, more than other areas of the body, may exhibit atrophic changes after prolonged treatment with potent topical corticosteroids. This must be borne in mind when treating such conditions as psoriasis, discoid lupus erythematosus and severe eczema. If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma might result. If clobetasol does enter the eye, the affected eye should be bathed in copious amounts of water. Topical steroids may be hazardous in psoriasis for a number of reasons including rebound relapses, development of tolerance, risk of generalised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin. If used in psoriasis, careful patient supervision is important. Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions which have become infected. Any spread of infection requires withdrawal of topical corticosteroid therapy and systemic administration of antimicrobial agents. Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressings, and so the skin should be cleansed before a fresh dressing is applied.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance):

Adverse reactions:

Immune system disorders: hypersensitivity. Local hypersensitivity reactions such as erythema, rash, pruritus, urticaria and allergic contact dermatitis may occur at the site of application and may resemble

symptoms of the condition under treatment. If signs of hypersensitivity appear, application should be stopped immediately.

Endocrine disorders: features of Cushing's syndrome. As with other topical corticosteroids, prolonged use of large amounts, or treatment of extensive areas can result in sufficient systemic absorption to produce the features of Cushing's syndrome. This effect is more likely to occur in infants and children, and if occlusive dressings are used. In infants, the nappy may act as an occlusive dressing. Provided the weekly dosage is less than 50g in adults, any suppression of the HPA axis is likely to be transient with a rapid return to normal values once the short course of steroid therapy has ceased. The same applies to children given proportionate dosage.

Vascular disorders: dilatation of the superficial blood vessels. Prolonged and intensive treatment with highly-active corticosteroid preparations may cause dilatation of the superficial blood vessels, particularly when occlusive dressings are used, or when skin folds are involved.

Skin and subcutaneous tissue disorders: local skin burning, local atrophy, striae, thinning, pigmentation changes, hypertrichosis, exacerbation of underlying symptoms, pustular psoriasis. Prolonged and intensive treatment with highly-active corticosteroid preparations may cause local atrophic changes, such as thinning and striae. Treatment of psoriasis with corticosteroids (or its withdrawal) is thought to have provoked the pustular form of the disease.

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I					
AT	I					
BE	I	Cutaneous		0.05%		62.5 mg
CZ	I	Cutaneous	Psoriasis, eczema, lichen planus, lupus erythematodes	0.05%		62.5 mg
ES	POM					
FR	I	Cutaneous	Psoriasis, dermatitis, eczema, lichen, pruritus Warning: do not use on large skin surfaces, do not use for long period of treatment			
HR	I	Cutaneous				30 g
IE	II					
IT	II					
LV	I					
MK	Not authorised					
PL	I	Cutaneous	Short treatment topical treatment of skin diseases responsive to treatment with corticosteroids, e.g. psoriasis, eczema. Available pharmaceutical forms: cream, ointment, shampoo, scalp application. Warning: do not use in children < 12 years	0.05%		50 ml
PT	II					
UK	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I

Criteria:
Therapeutic indications
Safety profile
Medical supervision

3.2 Paediatric use: contraindicated in dermatoses in children under one year of age, including dermatitis and napkin eruptions.

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Halcinonide

1.2 ATC Code: D07AD02 - Corticosteroids, plain; corticosteroids, very potent (group IV)

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
IT	II					
MK	Not authorised					
PL	Not authorised					
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Prednisolone and antiseptics

1.2 ATC Code: D07BA01 - Corticosteroids, combinations with antiseptics; corticosteroids, weak, combinations with antiseptics

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	I	Cutaneous	Dermatomycosis, erythrasms, pyodermia, eczema			
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
IT	Not authorised					
MK	Not authorised					
PL	Not authorised					
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Hydrocortisone and antiseptics

1.2 ATC Code: D07BA04 - Corticosteroids, combinations with antiseptics; corticosteroids, weak, combinations with antiseptics

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	POM					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
IT	Not authorised					
MK	Not authorised					
PL	I	Cutaneous	Treatment of purulent skin infections Combination product: hydrocortisone + chlorquinaldol. MS: in 1g: 30mg chlorquinaldol + 10mg hydrocortisone; MQP: 5g ointment. Warning: special attention in pregnant women and children < 12 years			
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Flumetasone and antiseptics

1.2 ATC Code: D07BB01 - Corticosteroids, combinations with antiseptics; corticosteroids, moderately potent, combinations with antiseptics

1.3 Therapeutic indications:
Flumetasone 0.2 mg + clioquinol 30 mg
Treatment of contact dermatitis, atopic dermatitis, stasis dermatitis, plaque psoriasis, seborrheic dermatitis (except of the face), insect bites and parasitic prurigo after aetiological treatment.

1.4 Posology and duration of treatment: treatment should be limited to 1–2 applications per day.

1.5 Pharmaceutical forms: ointment/cream

1.6 Contraindications: hypersensitivity to the active substances, primitive bacterial infections, viral, fungal or parasitic, injury ulcerated, acne vulgaris, rosacea, application on the eyelids (risk of glaucoma).

1.7 Relevant warnings: do not use on large skin surfaces, do not use for long period of treatment.
In case of bacterial or fungal infection steroid responsive dermatosis, antibacterial or antifungal treatment should precede the use of the corticosteroid treatment.
If a local intolerance occurs, treatment should be discontinued and the cause must be sought.
Not recommended in children < 2 years.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance):
Adverse effects due to flumetasone:
Prolonged use of corticosteroids of moderate activity may result in skin atrophy, telangiectasias (especially on the face), stretch marks (especially at the root of the members, and more likely to occur in adolescents), secondary ecchymotic purpura atrophy, skin fragility.
On the face, corticosteroids can cause perioral dermatitis or aggravate rosacea.
Delayed wound healing, pressure ulcers, leg ulcers can be observed.
Risk of systemic effects.
Acneiform or pustular eruptions, hypertrichosis, depigmentation have been reported.
Secondary infections, especially under occlusive dressing or in the folds and allergic contact dermatitis have been reported during use of topical corticosteroids.
Adverse effects due to clioquinol: risk of hypersensitivity, yellowing of the skin, quickly disappearing.

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	I	Cutaneous	Psoriasis, dermatitis, eczema, lichen, pruritus			

			Warning: do not use on large skin surfaces, do not use for long period of treatment			
HR	Not authorised					
IE	Not authorised					
IT	II		Available combination product: flumetasone 0.2 mg + clioquinol 30 mg			
PL	I	Cutaneous	Treatment of dry skin inflammations, responsive to glucocorticoid therapy, running with hyperkeratosis and persistent itching, complicated by bacterial infections Available combination product: flumetasone 0.2 mg + clioquinol 30mg. Available pharmaceutical forms: ointment. Warning: do not use in children < 2 years			
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I (1)

Criteria:
Therapeutic indications
Safety profile
Medical supervisions

3.2 Paediatric use: Not recommended in children < 2 years.

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Desonide and antiseptics

1.2 ATC Code: D07BB02 - Corticosteroids, combinations with antiseptics; corticosteroids, moderately potent, combinations with antiseptics

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
MK	Not authorised					
PL	Not authorised					
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Triamcinolone and antiseptics

1.2 ATC Code: D07BB03 - Corticosteroids, combinations with antiseptics; corticosteroids, moderately potent, combinations with antiseptics

1.3 Therapeutic indications: triamcinolone/salicylic acid**:** psoriasis vulgaris, eczema, pruritic dermatoses in hairy parts of the body, seborrheic dermatitis.

1.4 Posology and duration of treatment: applied to the affected areas 2 or 3 times a day to relieve the symptoms, then 1 to 2 times daily until healed. Between applications must be an interval of at least 4 hours.

1.5 Pharmaceutical forms: cutaneous solution.

1.6 Contraindications: hypersensitivity to the active substances, in cutaneous tuberculosis, chickenpox, herpes and other viral skin manifestations. It must not be used on children under 12 years.

1.7 Relevant warnings: triamcinolone may be absorbed in sufficient amounts to cause systemic corticosteroids effects, if applied to large areas, to broken skin or under occlusive dressings. Systemic absorption of topical corticosteroids has produced reversible HPA axis suppression, manifestation of Cushing's syndrome hyperglycaemia, and glucosuria in some patients. Generalised dermatological conditions may require systemic corticosteroid therapy. Extended or recurrent application may increase the risk of contact sensitisation and should be avoided. Avoid prolonged use on the face (and keep away from eyes).Caution should also be applied when using this preparation on the periorbital area of the face, as it can induce ocular complications that include cataract, glaucoma, retarded healing or corneal abrasion, extension of herpetic infection, and increased susceptibility of bacterial and fungal infection. It should be used with caution in patients with psoriasis as it may result in rebound relapses following the development of tolerance, including generalised pustular psoriasis. It may also result in local and systemic toxicity due to impaired barrier function of the skin. Absorption is more likely after repeated applications, possibly by greater skin permeability in psoriatic areas than normal skin. Use in cases where the approved indication/s co-exist with psoriasis.
Paediatric use: paediatric patients may demonstrate a greater susceptibility to topical corticosteroid induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio and are also therefore more susceptible to systemic toxicity. HPA axis suppression (and Addisonian crisis upon withdrawal), Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Avoid prolonged use in children and use under specialist supervision. Chronic corticosteroids therapy may interfere with growth and development of children.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance):
Occasionally - hypersensitivity at the application site: erythema, pruritus, urticaria.
In case of long term use - skin atrophy, striae, telangiectasia, increased photosensitivity, changes in skin pigmentation, hypertrichosis, perioral dermatitis.
After absorption of higher doses - undesirable systemic corticosteroid effects.

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I					
AT	Not authorised					
CZ	I					
DK	II					
ES	Not authorised					
FR	Not authorised					
HR	I					
IT	Not authorised					
LV	Deleted (commercial)					
PL	I					
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I

Criteria:
Therapeutic indications
Safety profile

3.2 Paediatric use: not in children < 12 years.

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Hydrocortisone butyrate and antiseptics

1.2 ATC Code: D07BB04 - Corticosteroids, combinations with antiseptics; corticosteroids, moderately potent, combinations with antiseptics

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
HU	Deleted					
IT	Not authorised					
MK	Not authorised					
PL	Not authorised					
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Betamethasone and antiseptics

1.2 ATC Code: D07BC01 - Corticosteroids, combinations with antiseptics; corticosteroids, potent, combinations with antiseptics

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
MK	Not authorised					
PL	I	Cutaneous	Treatment of skin diseases responsive to treatment with corticosteoids or accompanied by secondary bacterial infections and/or fungal infections Available combination product: betamethasone valerate + clioquinol. Available pharmaceutical forms: cream and ointment. MS: in 1 g: 1.22 mg betamethasone + 30 mg clioquinol. Warning: do not use in children < 1 year in the treatment of chronic inflammatory skin diseases (including diaper dermatitis)	0.122%		15 g

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Fluocinolone acetonide and antiseptics

1.2 ATC Code: D07BC02 - Corticosteroids, combinations with antiseptics; corticosteroids, potent, combinations with antiseptics

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
IT	Not authorised					
MK	Not authorised					
PL	Not authorised					
RO	Withdrawn					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Fluocortolone and antiseptics

1.2 ATC Code: D07BC03 - Corticosteroids, combinations with antiseptics; corticosteroids, potent, combinations with antiseptics

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
MK	Not authorised					
PL	Not authorised					
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Diflucortolone and antiseptics

1.2 ATC Code: D07BC04 - Corticosteroids, combinations with antiseptics; corticosteroids, potent, combinations with antiseptics

1.3 Therapeutic indications: dermatosis

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	POM					
FR	I	Cutaneous	Psoriasis, dermatitis, eczema, lichen, pruritus Warning: do not use on large skin surfaces, do not use for long period of treatment			
HR	Not authorised					
IE	II					
IT	Not authorised					
PL	Not authorised					
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Corticosteroids very potent, combinations with antiseptics (no specific active ingredients are included in this sub-group)

1.2 ATC Code: D07BD - Corticosteroids, combinations with antiseptics

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions: no information available in *Melclass* database.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Hydrocortisone and antibiotics

1.2 ATC Code: D07CA01 - Corticosteroids, combinations with antibiotics; corticosteroids, weak, combinations with antibiotics

1.3 Therapeutic indications: in eczema and dermatitis with secondary bacterial infections, including atopic eczema, primary irritant dermatitis and allergic and seborrhoeic dermatitis where the organisms responsible are known to be or believed to be sensitive to antibiotic.

1.4 Posology and duration of treatment: adults and children: *Uncovered lesions:* a small quantity should be applied to the affected area twice daily until a satisfactory response is obtained. A single treatment course should not normally exceed 2 weeks. *Covered lesions:* less frequent applications may be adequate.

1.5 Pharmaceutical forms: cream

1.6 Contraindications: known hypersensitivity to antibiotic or hydrocortisone acetate; primary skin infections caused by bacteria, fungi or viruses (such as herpes or varicella), skin manifestations in relation to tuberculosis or syphilis, perioral dermatitis and rosacea.

1.7 Relevant warnings: long term continuous topical therapy should be avoided. Adrenal suppression can occur even without occlusion. Atrophic changes may occur on the face and to a lesser degree in other parts of the body, after prolonged treatment with topical steroids. Caution should be exercised, if the cream is used near the eye. Glaucoma might result if the preparation enters the eye. Systemic chemotherapy is required if bacterial infection persists. As with all antibiotics, extended or recurrent application may increase the risk of developing antibiotic resistance. Steroid-antibiotic combinations should not be continued for more than 7 days in the absence of any clinical improvement since in this situation occult extension of the infection may occur due to the masking of the steroid. Similarly, steroids may also mask hypersensitivity reactions. Steroid-antibiotic combinations are not recommended in the following conditions: atrophic skin, cutaneous ulcer, acne vulgaris, fragile skin veins and perianal and genital pruritis. Contact with open wounds and mucous membranes should be avoided. As with all corticosteroids, prolonged use on the face should be avoided.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): the most frequently reported adverse drug reactions are various skin reactions and in particular application site reactions. Allergic reactions and contact dermatitis have been reported.

Immune system disorders: not known: allergic reactions.

Skin and subcutaneous tissue disorders:
Uncommon: skin irritation, skin burning sensation, skin stinging sensation, pruritus, eczema aggravated.
Not known: rash, allergic contact dermatitis, depigmentation.

Class effect: undesirable effects observed for corticosteroids include: skin atrophy, telangiectasia and skin striae, especially during prolonged application, folliculitis, hypertrichosis, perioral dermatitis, allergic contact dermatitis, depigmentation and adrenocortical suppression.

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I					
AT	I					
BE	POM	Cutaneous	Available combination products: hydrocortisone + fusidic acid - list classification: POM; hydrocortisone + oxytetracycline - list classification: OTC	1%		150 mg
CZ	I	Cutaneous	Infected inflammatory dermatitis			
DK	Not authorised					
ES	POM					
FR	Not authorised					
HR	I					
IE	POM					
LV	I					
MK	I	Cutaneous	Eczema and dermatitis of different types where secondary bacterial infection may occur, including allergic dermatitis, insect bite reaction. Available combination product: hydrocortisone (MS: 1%) + oxytetracycline (MS: 3%). Warnings: it should not be used more than 7 days unless there is a relief of symptoms of disease. The use of oxytetracycline and other antibiotics can result in excessive growth of resistant microorganisms: careful monitoring of patients needed.	1%		20 g
PL	I	Cutaneous	Available combination products: Product 1: hydrocortisone 10mg + oxytetracycline 30mg; Product 2: hydrocortisone 10mg + natamycin 3500IU + neomycin 10mg. Available pharmac. forms: Product 1: ointment and cream (MQP: 15g); Product 2: ointment (MQP: 10g) Product 1: short-term treatment of superficial skin conditions responsive to corticosteroid treatment, with concomitant secondary infections caused by bacteria or fungi. Product 2: Local treatment of skin inflammation complicated by bacterial infections Warnings: do not use on face, in the genital area and the anus or on broken skin; do not use in children	1%		10 g and 15 g (depending on pharmaceutical form)
RO	I (1)					
SI	I					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I

Criteria:
Therapeutic indications
Safety profile
Medical supervision

3.2 Paediatric use: normally a single treatment course should not exceed 2 weeks.

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Methylprednisolone and antibiotics

1.2 ATC Code: D07CA02 - Corticosteroids, combinations with antibiotics; corticosteroids, weak, combinations with antibiotics

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
MK	Not authorised					
PL	Not authorised					
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Prednisolone and antibiotics

1.2 ATC Code: D07CA03 - Corticosteroids, combinations with antibiotics; corticosteroids, weak, combinations with antibiotics

1.3 Therapeutic indications: eczema and dermatitis with secondary bacterial infections, including atopic eczema, primary irritant dermatitis and allergic and seborrhoeic dermatitis where the organisms responsible are known to be or believed to be sensitive to antibiotic.

1.4 Posology and duration of treatment: the ointment should be applied sparingly to the affected area, two or three times daily. Treatment should be limited to seven days.

1.5 Pharmaceutical forms: ointment

1.6 Contraindications: *related to prednisolone:* rosacea, acne vulgaris, perioral dermatitis, perianal and genital pruritus, primary cutaneous viral infections (e.g. herpes simplex, chickenpox), skin manifestations in relation to tuberculosis or syphilis. Use is not indicated in treatment of primary infected skin lesions caused by infection with fungi or bacteria; primary or secondary infections due to yeast.

Related to neomycin sulfate: dermatoses in children under 2 years of age, including dermatitis and napkin eruptions. A possibility of increased absorption exists in very young children, thus it is not recommended for use in neonates and infants (up to 2 years). In neonates and infants, absorption by immature skin may be enhanced, and renal function may be immature. Preparations containing neomycin should not be used for the treatment of otitis externa when the ear drum is perforated, because of the risk of ototoxicity. Due to the known ototoxic and nephrotoxic potential of neomycin sulfate, the use in large quantities or on large areas for prolonged periods of time is not recommended in circumstances where significant systemic absorption may occur.

Related to active substances: hypersensitivity to prednisolone or to antibiotic.

1.7 Relevant warnings: long-term continuous topical therapy should be avoided where possible, particularly in children, as adrenal suppression, with or without clinical features of Cushing's syndrome, can occur even without occlusion. In this situation, topical steroids should be discontinued gradually under medical supervision because of the risk of adrenal insufficiency. If infection persists, systemic chemotherapy is required. Steroid-antibiotic combinations should not be continued for more than 7 days in the absence of any clinical improvement since in this situation occult extension of the infection may occur due to the masking of the steroid. Similarly, steroids may also mask hypersensitivity reactions. Withdraw topical corticosteroid if there is a spread of infection. Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressings, and the skin should be cleansed before a fresh dressing is applied. Avoid prolonged application to the face. The face, more than other areas of the body, may exhibit atrophic changes after prolonged treatment with potent topical corticosteroids. This must be borne in mind when treating such conditions as severe eczema. If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma might result. If the cream/ointment does enter the eye, the affected eye should be bathed in copious amounts of water. Extended or recurrent application may increase the risk of contact sensitisation. Following significant systemic absorption, aminoglycosides such as neomycin can cause irreversible ototoxicity; neomycin/ gentamycin has nephrotoxic potential. In renal impairment the plasma clearance of neomycin/gentamycin is reduced. Products which contain antimicrobial agents should not be diluted.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I					
AT	Not authorised					
BE	Not authorised					
CZ	Deleted					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
HU	Deleted					
IE	POM					
MK	Not authorised					
PL	I	Cutaneous	Treatment of exudative inflammations of the skin of various etiologies, responsive to glucocorticosteroids, complicated by secondary bacterial infections Available combination products: prednisolone 5mg + neomycin 5mg. Warnings: do not use on large areas of skin; do not use in children < 2 years	0.05%		10 g
RO	I (1)	Cutaneous	Available combination: prednisolone + neomycin. MS: 250 mg prednisolone + 50 mg neomycin/g; MDD: 3-4 applications per day for 8 days; MQP: 10g prednisolone + 2g neomycin.			

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I

Criteria:
Therapeutic indications
Safety profile
Medical supervision

3.2 Paediatric use: *related to neomycin sulfate*: dermatoses in children under 2 years of age.

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Triamcinolone and antibiotics (e.g. chlortetracycline)

1.2 ATC Code: D07CB01 - Corticosteroids, combinations with antibiotics; corticosteroids, moderately potent, combinations with antibiotics

1.3 Therapeutic indications: triamcinolone/chlortetracycline: treatment of secondarily infected atopic dermatitis, contact dermatitis, eczema, neurodermatitis, otitis externa, seborrhoeic dermatitis, varicose eczema, vesiculo-pustular dermatitis. It may also be used in the treatment of infected insect bites.

1.4 Posology and duration of treatment: adults, children over 8 years and the elderly: The ointment should be applied sparingly to the affected area, two or three times daily. Treatment should be limited to seven days.

1.5 Pharmaceutical forms:

1.6 Contraindications: in tuberculous, fungal or viral lesions of the skin (herpes simplex, vaccinia and varicella), and primary bacterial infections, e.g. impetigo, pyoderma, furunculosis, in acne vulgaris rosacea, perioral dermatitis and widespread plaque psoriasis; hypersensitivity to triamcinolone or to antibiotic.

1.7 Relevant warnings: triamcinolone may be absorbed in sufficient amounts to cause systemic corticosteroids effects, if applied to large areas, to broken skin or under occlusive dressings. Systemic absorption of topical corticosteroids has produced reversible HPA axis suppression, manifestation of Cushing's syndrome hyperglycaemia, and glucosuria in some patients. Minor degrees of adrenal suppression may occur when the ointment is applied over relatively small areas under an occlusive dressing. Occlusion should not be used when treating conditions of the face. Chlortetracycline, like other tetracycline-class antibiotics, may cause foetal harm when administered to a pregnant woman. The use of corticosteroids on infected areas should be continuously and carefully observed, bearing in mind the potential spreading of infections (caused by organisms not sensitive to chlortetracycline) by anti-inflammatory corticosteroids. It may be advisable to discontinue corticosteroid therapy and/or initiate alternative antibacterial measures in these circumstances. Generalised dermatological conditions may require systemic corticosteroid therapy. Steroid-antibiotic combinations should not be continued for more than 7 days in the absence of any clinical improvement, since in this situation occult extension of infection may occur due to the masking effect of the steroid. Extended or recurrent application may increase the risk of contact sensitisation and should be avoided. Hypersensitivity reactions to the anti-infective component may be masked by the presence of the corticosteroid. Phototoxic reactions can occur in individuals using chlortetracycline, and are characterised by severe burns of exposed surfaces resulting from direct exposure of patients to sunlight during therapy with chlortetracycline. Patients exposed to direct sunlight or ultraviolet light (artificial sunlight) should be advised that this reaction can occur, and treatment should be discontinued at the first evidence of erythema of the skin. Avoid prolonged use on the face (and keep away from eyes).Caution should also be applied when using this preparation on the periorbital area of the face, as it can induce ocular complications that include cataract, glaucoma, retarded healing or corneal abrasion, extension of herpetic infection, and increased susceptibility to bacterial and fungal infection. It should be used with caution in patients with psoriasis as it may result in rebound relapses following the development of tolerance, including generalised pustular psoriasis. It may also result in local and systemic toxicity due to impaired barrier function of the skin. Absorption is more likely after repeated applications, possibly by greater skin permeability in psoriatic areas than normal skin. Use in cases where the approved indication/s co-exist with psoriasis.
Paediatric use: paediatric patients may demonstrate a greater susceptibility to topical corticosteroid induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio and are also therefore more susceptible to systemic toxicity. HPA axis suppression (and Addisonian crisis upon withdrawal), Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Avoid prolonged use in children and use under specialist supervision. Chronic corticosteroids therapy may interfere with growth and development of children. The use of drugs of the tetracycline class during tooth development may result in permanent discolouration of the teeth. Enamel hypoplasia has also been reported. Tetracycline drugs, therefore, should not be used during tooth development unless other drugs are not likely to be effective or are contraindicated. To reduce the theoretical risk of damage to permanent

dentition by tetracyclines, the ointment should not be used in children under 8 years of age, unless other drugs are likely to be ineffective or are contra-indicated.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance):

Adverse reactions:

Immune system disorders: hypersensitivity

Skin and subcutaneous tissue disorders: application site reactions, including contact dermatitis, skin atrophy, steroid purpura, striae, skin fragility, exfoliative dermatitis, burning sensation, acneiform eruption, folliculitis, rosacea, periocular and perioral dermatitis, delayed wound healing, granulomas, telangiectases, erythema, hypopigmentation, hypertrichosis, masking or aggravation of dermatophyte infection and secondary infection or aggravation of existing infection, photosensitivity, rash, urticaria, pruritus. If an allergic reaction occurs, medication should be discontinued. Use of topical corticosteroids, such as triamcinolone, in the periorbital region may result in ocular complications. Under certain circumstances sufficient amounts of topical corticosteroids, such as triamcinolone, can be absorbed to cause systemic corticosteroid effects including adrenal suppression and Cushing's syndrome. Cessation of topical steroid therapy after an extended treatment period can result in Addisonian crisis. Chlortetracycline, like other tetracycline-class antibiotics, may cause foetal harm when administered to a pregnant woman, and may cause permanent discolouration of the teeth during development in children up to the age of 8 years.

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I					
AT	I (1)					
BE	OTC, see Annex III	Cutaneous	Combination product (with gramicidin)			
ES	POM					
HR	Not authorised					
IT	II					
LV	II					
PL	I	Cutaneous	Local treatment of skin inflammation complicated by bacterial infection susceptible to tetracycline Available combination product: triamcinolone 0.58mg + tetracycline 23.12mg. Available pharmaceutical form: aerosol	0.058%		17.3 g
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I

Criteria:

Therapeutic indications
Safety profile
Medical supervision

3.2 Paediatric use: treatment should be limited to seven days and requires medical supervision.

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Fluprednidene and antibiotics

1.2 ATC Code: D07CB02 - Corticosteroids, combinations with antibiotics; corticosteroids, moderately potent, combinations with antibiotics

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	I					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
MK	Not authorised					
PL	Not authorised					
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Fluorometholone and antibiotics

1.2 ATC Code: D07CB03 - Corticosteroids, combinations with antibiotics; corticosteroids, moderately potent, combinations with antibiotics

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
MK	Not authorised					
PL	Not authorised					
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Dexamethasone and antibiotics

1.2 ATC Code: D07CB04 - Corticosteroids, combinations with antibiotics; corticosteroids, moderately potent, combinations with antibiotics

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
IT	Not authorised					
MK	Not authorised					
PL	I	Cutaneous	Treatment of skin inflammations complicated by susceptible bacteria Available combination products: dexamethasone 0.28mg + neomycin 1.38mg. Available pharmaceutical forms: aerosol. Warnings: do not use on reactions to vaccinations.	0.028%		16.25 g
SI	I					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Flumethasone and antibiotics

1.2 ATC Code: D07CB05 - Corticosteroids, combinations with antibiotics; corticosteroids, moderately potent, combinations with antibiotics

1.3 Therapeutic indications: treatment of exudative inflammation of the skin, especially of allergic aetiology, responsive to glucocorticoid therapy, with hyperkeratosis and persistent itching, complicated by secondary bacterial infections.

1.4 Posology and duration of treatment: *flumethasone/neomycin:*

1.5 Pharmaceutical forms: cream

1.6 Contraindications: *related to flumethasone:* bacterial, viral, fungal infections, acne or rosacea, perianal lesions; not for large surfaces of the skin; not for burns.

Related to neomycin: in children under 2 years of age. A possibility of increased absorption exists in very young children, thus it is not recommended for use in neonates and infants (up to 2 years). In neonates and infants, absorption by immature skin may be enhanced, and renal function may be immature. Due to the known ototoxic and nephrotoxic potential of neomycin, the use in large quantities or on large areas for prolonged periods of time is not recommended in circumstances where significant systemic absorption may occur.

Related to active substances: hypersensitivity to betamethasone or to antibiotics.

1.7 Relevant warnings: long-term continuous topical therapy should be avoided where possible, particularly in children, as adrenal suppression, with or without clinical features of Cushing's syndrome, can occur even without occlusion. In this situation, topical steroids should be discontinued gradually under medical supervision because of the risk of adrenal insufficiency. If infection persists, systemic chemotherapy is required. As with all antibiotics, extended or recurrent application may increase the risk of developing antibiotic resistance. Steroid-antibiotic combinations should not be continued for more than 7 days in the absence of any clinical improvement since in this situation occult extension of the infection may occur due to the masking of the steroid. Similarly, steroids may also mask hypersensitivity reactions. Withdraw topical corticosteroid if there is a spread of infection. Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressings, and the skin should be cleansed before a fresh dressing is applied. Avoid prolonged application to the face. The face, more than other areas of the body, may exhibit atrophic changes after prolonged treatment with potent topical corticosteroids. If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma might result. If the cream does enter the eye, the affected eye should be bathed in copious amounts of water. Extended or recurrent application may increase the risk of contact sensitization. Following significant systemic absorption, aminoglycosides such as neomycin can cause irreversible ototoxicity; neomycin has nephrotoxic potential. In renal impairment the plasma clearance of neomycin is reduced.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): skin atrophy, telangiectasia, and skin striae, especially during prolonged application, folliculitis, hypertrichosis, perioral dermatitis, allergic contact dermatitis, depigmentation, glaucoma and adrenocortical suppression.

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
IT	II					
MK	Not authorised					
PL	I	Cutaneous	Treatment of exudative inflammation of the skin, especially of allergic aetiology, responsive to glucocorticoid therapy, running with hyperkeratosis and persistent itching, complicated by secondary bacterial infections Available combination products: flumetasone 0.2mg + neomycin 5mg. Available pharmaceutical form: cream. Warnings: do not use in children < 2 years	0.002%		15 g
SI	I					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I (1)

Criteria:
Therapeutic indications
Safety profile
Medical supervision

3.2 Paediatric use: not for children < 2 years.

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Betamethasone and antibiotics

1.2 ATC Code: D07CC01 - Corticosteroids, combinations with antibiotics; corticosteroids, potent, combinations with antibiotics

1.3 Therapeutic indications:

Betamethasone with fusidic acid: treatment of eczematous dermatoses including atopic eczema, discoid eczema, stasis eczema and seborrhoeic eczema when secondary bacterial infection is confirmed or suspected.

Betamethasone with neomycin/gentamicin: treatment of eczema in adults and children (aged 2 years and over), including atopic and discoid eczemas; prurigo nodularis; psoriasis (excluding widespread plaque psoriasis); neurodermatoses including lichen simplex and lichen planus; seborrhoeic dermatitis; contact sensitivity reactions; insect bite reactions; and anal and genital intertrigo.

1.4 Posology and duration of treatment:

Betamethasone with fusidic acid: adults and children aged 6 years and over: A small quantity should be applied to the affected area twice daily until a satisfactory response is obtained. A single treatment course should not normally exceed 2 weeks. In the more resistant lesions the effect of cream can be enhanced by occlusion with polyethylene film. Overnight occlusion is usually adequate.

Betamethasone with neomycin/gentamicin: treatment should not be continued for more than 7 days without medical supervision. A small quantity should be applied to the affected area two or three times daily until improvement occurs. It may then be possible to maintain improvement by applying once a day, or even less often. It is suitable for use in children (2 years and over) at the same dose as adults. When used in children, courses should be limited to 5 days, if possible.

1.5 Pharmaceutical forms: cream/ointment.

1.6 Contraindications:

Related to bethametasone: rosacea, acne vulgaris, perioral dermatitis, perianal and genital pruritus, primary cutaneous viral infections (e.g. herpes simplex, chickenpox), skin manifestations in relation to tuberculosis or syphilis. Use is not indicated in treatment of primary infected skin lesions caused by infection with fungi or bacteria; primary or secondary infections due to yeast.

Related to neomycin sulfate/gentamycin sulfate: dermatoses in children under 2 years of age, including dermatitis and napkin eruptions. A possibility of increased absorption exists in very young children, thus it is not recommended for use in neonates and infants (up to 2 years). In neonates and infants, absorption by immature skin may be enhanced, and renal function may be immature. Preparations containing neomycin should not be used for the treatment of otitis externa when the ear drum is perforated, because of the risk of ototoxicity. Due to the known ototoxic and nephrotoxic potential of neomycin sulfate/gentamycin sulfate, the use in large quantities or on large areas for prolonged periods of time is not recommended in circumstances where significant systemic absorption may occur.

Related to active substances: hypersensitivity to betamethasone or to antibiotic.

1.7 Relevant warnings: long-term continuous topical therapy should be avoided where possible, particularly in infants and children, as adrenal suppression, with or without clinical features of Cushing's syndrome, can occur even without occlusion. In this situation, topical steroids should be discontinued gradually under medical supervision because of the risk of adrenal insufficiency. If infection persists, systemic chemotherapy is required. Bacterial resistance has been reported to occur with the use of fusidic acid. As with all antibiotics, extended or recurrent application may increase the risk of developing antibiotic resistance. Steroid-antibiotic combinations should not be continued for more than 7 days in the absence of any clinical improvement since in this situation occult extension of the infection may occur due to the masking of the steroid. Similarly, steroids may also mask hypersensitivity reactions. Withdraw topical corticosteroid if there is a spread of infection. Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressings, and the skin should be cleansed before a fresh dressing is applied. Avoid prolonged application to the face. The face, more than other areas of the body, may exhibit atrophic changes after prolonged treatment with potent topical corticosteroids. This must be borne in mind

when treating such conditions as psoriasis, discoid lupus erythematosus and severe eczema. If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma might result. If the cream/ointment does enter the eye, the affected eye should be bathed in copious amounts of water. Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses, development of tolerance, risk of generalised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin. If used in psoriasis careful patient supervision is important. Extended or recurrent application may increase the risk of contact sensitisation. Following significant systemic absorption, aminoglycosides such as neomycin/gentamycin can cause irreversible ototoxicity; neomycin/ gentamycin has nephrotoxic potential. In renal impairment the plasma clearance of neomycin/gentamycin is reduced. Products which contain antimicrobial agents should not be diluted.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance):

Adverse reactions reported for betamethasone/fusidic acid

Immune system disorders: not known: allergic reaction

Skin and subcutaneous tissue disorders:
Uncommon: skin irritation, skin burning sensation, pruritus, eczema aggravated, skin stinging sensation, erythema
Rare: urticaria, dry skin
Not known: contact dermatitis, rash, telangiectasia

Class effect: undesirable effects observed for corticosteroids include: skin atrophy, telangiectasia, and skin striae, especially during prolonged application, folliculitis, hypertrichosis, perioral dermatitis, allergic contact dermatitis, depigmentation, glaucoma and adrenocortical suppression.

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I					
AT	I					
BA	I					
BE	I	Cutaneous		0.1%		30 mg
CZ	I	Cutaneous		Infected inflammatory dermatitis		
ES	POM					
FR	Not authorised					
HR	I					
IE	POM					
IT	II					
LV	I					
MK	I	Cutaneous	Skin diseases responsive to local therapy with corticosteroids, which have or may develop primary or secondary bacterial infections Warnings: Long term continuous therapy should be avoided in all patients irrespective of their age; local and systemic toxicity may occur following long continuous use on large areas of damaged skin, in flexures or under a	0.05%		15 g

			polythene occlusion.			
PL	I	Cutaneous	Treatment of skin diseases responsive to corticosteroid therapy, complicated by secondary bacterial infections Available combination products: betamethasone 1.22mg + neomycin 5mg (in 1g); betamethasone 0.5mg + gentamycin 1mg (in 1g). Available pharmaceutical forms: cream and ointment (MQP: 15g and 30 g). Warnings: no long-term use in high doses or large skin areas	0.5mg and 1.22mg		15g and 30g
RO	I					
SL	I					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I

Criteria:
Therapeutic indications
Safety profile
Medical supervision

3.2 Paediatric use: in children of 2 years and over. When used in children, courses should be limited to 5 days, if possible.

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Fluocinolone acetonide and antibiotics

1.2 ATC Code: D07CC02 - Corticosteroids, combinations with antibiotics; corticosteroids, potent, combinations with antibiotics

1.3 Therapeutic indications: treatment of eczematous dermatoses in adults and children over 2 years, including atopic eczema, discoid eczema, stasis eczema and seborrhoeic eczema when secondary bacterial infection is confirmed or suspected; psoriasis (excluding widespread plaque psoriasis); neurodermatoses including lichen simplex and lichen planus; contact sensitivity reactions; insect bite reactions; and anal and genital intertrigo.

1.4 Posology and duration of treatment: treatment should not be continued for more than 7 days without medical supervision. A small quantity should be applied to the affected area two or three times daily until improvement occurs. It may then be possible to maintain improvement by applying once a day. It is suitable for use in children (2 years and over) at the same dose as adults. When used in children, courses should be limited to 5 days, if possible.

1.5 Pharmaceutical forms: cream/ointment.

1.6 Contraindications:

Related to fluocinolone acetonide: rosacea, acne vulgaris, perioral dermatitis, perianal and genital pruritus, primary cutaneous viral infections (e.g. herpes simplex, chickenpox), skin manifestations in relation to tuberculosis or syphilis. Use is not indicated in treatment of primary infected skin lesions caused by infection with fungi or bacteria; primary or secondary infections due to yeast.

Related to neomycin sulfate (if the antibiotic is neomycin sulfate or another aminoglycoside: dermatoses in children under 2 years of age, including dermatitis and napkin eruptions. A possibility of increased absorption exists in very young children, thus not recommended for use in neonates and infants (up to 2 years). In neonates and infants, absorption by immature skin may be enhanced, and renal function may be immature. Preparations containing neomycin should not be used for the treatment of otitis externa when the ear drum is perforated, because of the risk of ototoxicity. Due to the known ototoxic and nephrotoxic potential of neomycin sulfate, the use in large quantities or on large areas for prolonged periods of time is not recommended in circumstances where significant systemic absorption may occur.

Related to active substances: hypersensitivity to fluocinolone acetonide or to antibiotics.

1.7 Relevant warnings: long-term continuous topical therapy should be avoided where possible, particularly in infants and children, as adrenal suppression, with or without clinical features of Cushing's syndrome, can occur even without occlusion. In this situation, topical steroids should be discontinued gradually under medical supervision because of the risk of adrenal insufficiency. If infection persists, systemic chemotherapy is required. Steroid-antibiotic combinations should not be continued for more than 7 days in the absence of any clinical improvement since in this situation occult extension of the infection may occur due to the masking of the steroid. Similarly, steroids may also mask hypersensitivity reactions. Withdraw topical corticosteroid if there is a spread of infection. Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressings, and the skin should be cleansed before a fresh dressing is applied. Avoid prolonged application to the face. The face, more than other areas of the body, may exhibit atrophic changes after prolonged treatment with potent topical corticosteroids. This must be borne in mind when treating such conditions as psoriasis, discoid lupus erythematosus and severe eczema. If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma might result. If the cream/ointment does enter the eye, the affected eye should be bathed in copious amounts of water. Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses, development of tolerance, risk of generalised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin. If used in psoriasis careful patient supervision is important. Extended or recurrent application may increase the risk of contact sensitisation. Following significant systemic absorption, aminoglycosides such as neomycin can cause irreversible ototoxicity; neomycin has nephrotoxic potential. In renal impairment the plasma clearance of neomycin is reduced. Products which contain antimicrobial agents should not be diluted.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): adverse reactions: prolonged and intensive treatment with highly active corticosteroid preparations may cause local atrophic changes in the skin such as thinning, striae, and dilatation of the superficial blood vessels, particularly when occlusive dressings are used or when skin folds are involved. As with other topical corticosteroids, prolonged use of large amounts or treatment of extensive areas can result in sufficient systemic absorption to produce suppression of the HPA axis and the clinical features of Cushing's syndrome. These effects are more likely to occur in infants and children, and if occlusive dressings are used. In infants the napkin may act as an occlusive dressing. In rare instances, treatment of psoriasis with corticosteroids (or its withdrawal) is thought to have provoked the pustular form of the disease. There are reports of local skin burning, pruritus, pigmentation changes, allergic contact dermatitis and hypertrichosis with topical steroids. Hypersensitivity cases in relation with preparations containing fluocinolone acetonide and an antibiotic have been reported. If signs of hypersensitivity appear, application should be stopped immediately. Exacerbation of symptoms may occur.

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	POM					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
IT	Not authorised					
MK	I	Cutaneous	Treatment of certain inflammatory, itchy or allergic skin conditions (e.g. eczema, dermatitis) when infection may be present Warnings: Not recommended for use in children under 1 year of age; drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.			15 g
PL	I	Cutaneous	Inflammation of the skin, complicated by secondary bacterial infections in patients with persistent itchy or hyperkeratosis, responsive to corticosteroids Available combination product: fluocinolone acetonide (MS: 0.25mg in 1g) + neomycin (MS: 5mg in 1g). Available pharmaceutical forms: cream and ointment. Warnings: do not use in children < 2 years; do not use under occlusion; do not use longer than 2 weeks	0.25 mg		15 g
RO	I (1)					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I

Criteria:
Therapeutic indications
Safety profile
Medical supervision

3.2 Paediatric use: in children over 2 years. When used in children, courses should be limited to 5 days, if possible.

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Fludroxycortide and antibiotics

1.2 ATC Code: D07CC03 - Corticosteroids, combinations with antibiotics; corticosteroids, potent, combinations with antibiotics

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
IT	Not authorised					
MK	Not authorised					
PL	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Beclometasone and antibiotics

1.2 ATC Code: D07CC04 - Corticosteroids, combinations with antibiotics; corticosteroids, potent, combinations with antibiotics

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	POM					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
IT	Not authorised					
MK	Not authorised					
PL	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Fluocinonide and antibiotics

1.2 ATC Code: D07CC05 - Corticosteroids, combinations with antibiotics; corticosteroids, potent, combinations with antibiotics

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	POM					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
IT	Not authorised					
MK	Not authorised					
PL	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Fluocortolone and antibiotics

1.2 ATC Code: D07CC06 - Corticosteroids, combinations with antibiotics; corticosteroids, potent, combinations with antibiotics

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
MK	Not authorised					
PL	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Clobetasol and antibiotics

1.2 ATC Code: D07CD01 - Corticosteroids, combinations with antibiotics; corticosteroids, very potent, combinations with antibiotics

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
IT	Not authorised					
MK	Not authorised					
PL	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Hydrocortisone

1.2 ATC Code: D07XA01 - Corticosteroids, other combinations; corticosteroids, weak, other combinations

1.3 Therapeutic indications:

Hydrocortisone/urea: treatment of dry ichthyotic, eczematous conditions of the skin, including atopic, infantile, chronic allergic and irritant eczema, asteatotic, hyperkeratotic and lichenified eczema, neurodermatitis and prurigo.

Hydrocortisone/crotamiton: relief of inflammation and pruritus associated with: irritant contact dermatitis, allergic contact dermatitis, insect bite reactions, mild to moderate eczema.

1.4 Posology and duration of treatment:

Hydrocortisone/urea: adults, children and the elderly: a small amount should be applied topically to the preferably dry affected areas twice daily. In resistant lesions occlusive dressings may be used.

Hydrocortisone/crotamiton: adults and children over 10: apply sparingly over a small area twice a day for a maximum period of 1 week. Occlusive dressings should not be used. Do not use in children under 10 years without medical advice.

1.5 Pharmaceutical forms: cream

1.6 Contraindications: primary bacterial, viral and fungal diseases of the skin and secondarily infected eczemas or intertrigo acne, perioral dermatitis, rosacea and, in general, should not be used on weeping surfaces; known hypersensitivity to hydrocortisone or urea.

Hydrocortisone/crotamiton: bacterial, viral or fungal infections of the skin; acute exudative dermatoses; application to ulcerated areas; use on the eyes/face, ano-genital region, broken or infected skin including cold sores, acne and athlete's foot; known hypersensitivity to hydrocortisone or crotamiton.

1.7 Relevant warnings:

Hydrocortisone/urea: caution should be exercised when using in children. In infants and children, long term continuous therapy should be avoided, as adrenal suppression can occur even without occlusion. Excessive absorption may occur when applied under napkins. Where possible treatment in infants should be limited to 5-7 days. Application to moist or fissured skin may cause temporary irritation. As with corticosteroids in general, prolonged application to the face and eyelids is undesirable and the cream should be kept away from the eyes.

Hydrocortisone/crotamiton: it should be used for not more than 7 days; long-term continuous topical therapy should be avoided since this can lead to adrenal suppression even without occlusion. Should not be allowed to come into contact with the conjunctiva and mucous membranes

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance):

Adverse reactions:

Hydrocortisone/urea: spread and worsening of untreated infection; thinning of the skin; irreversible striae atrophicae and telangiectasia; contact dermatitis, perioral dermatitis; acne; mild depigmentation which may be reversible. Atrophic changes may occur in intertriginous areas or nappy areas in young children.

Hydrocortisone/crotamiton: occasionally at the site of application signs of irritation such as a burning sensation, itching, contact dermatitis/contact allergy may occur. Treatment should be discontinued if patients experience severe irritation or sensitisation.

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
IT	Not authorised					
MK	Not authorised					
PL	Not authorised					
RO	Not authorised					
UK	I (1) + exemption Annex III	Cutaneous	For use either alone or in conjunction with crotamiton in irritant dermatitis, contact allergic dermatitis, insect bite reactions, mild to moderate eczema. For use in combination with other suitable active ingredients for athlete's foot and candidal intertrigo; for intertrigo, in adults and children not less than 10 years	1%		15g

* Melclass database - Available at: http://www.edqm.eu/melclass/

Corticosteroids for topical use for treatment of haemorrhoids are classified under C05A.

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Prednisolone

1.2 ATC Code: D07XA02 - Corticosteroids, other combinations; corticosteroids, weak, other combinations

1.3 Therapeutic indications: *prednisolone/salicylic acid:* symptomatic treatment of steroid-responsive dermatoses with scaly keratotic component especially at the scalp in hairy areas and folds.

1.4 Posology and duration of treatment: 1-2 applications daily.

1.5 Pharmaceutical forms: cutaneous solution.

1.6 Contraindications: primary bacterial, viral and fungal diseases of the skin, acne, rosacea; known hypersensitivity to prednisolone or to the other component.

1.7 Relevant warnings: long-term continuous topical therapy should be avoided where possible, particularly in infants and children, as adrenal suppression, with or without clinical features of Cushing's syndrome, can occur even without occlusion. In this situation, topical steroids should be discontinued gradually under medical supervision because of the risk of adrenal insufficiency. Avoid contact with the eyes and mucous membranes. If irritation or sensitisation develops, treatment should be discontinued. If concomitant skin infections are present or develop, an appropriate antifungal or antibacterial agent should be used.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): adverse reactions: continuous application without interruption may result in local atrophy of the skin, striae and superficial vascular dilation. Adverse reactions that have been reported with the use of topical corticosteroids include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation and allergic contact dermatitis. The following may occur more frequently with the use of occlusive dressings: maceration of the skin, secondary infection, skin atrophy, striae and miliaria. In addition, prolonged use of salicylic acid preparations may cause dermatitis.

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I					
AT	I					
BE	Not authorised					
CZ	I	Cutaneous	Psoriasis in scalp, seborrheic dermatitis, alopecia	0.2%		0.2g
ES	Not authorised					
FR	Not authorised					
HR	I	Cutaneous				
IE	Not authorised					
LV	I					
MK	Not authorised					
PL	I	Cutaneous	Available combination products: 1. prednisolone 2mg + salicylic acid 4mg; 2. prednisolone 2mg + salicylic acid 4mg + estradiol 5mg. Available pharmac. form: liquid for skin use. Warning: for	0.2%		100ml

			patients > 18 years Indications: Product 1: hair loss in the course of diseases such as scalp psoriasis, seborrhea, alopecia areata, etc. Product 2: Alopecia, particularly androgens-dependent			
RO	I					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I

Criteria:
Therapeutic indications
Safety profile

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Flumetasone

1.2 ATC Code: D07XB01 - Corticosteroids, other combinations; corticosteroids, moderately potent, other combinations

1.3 Therapeutic indications: *flumetasone /salicylic acid*: inflammation of the skin, especially allergic, with persistent itching or hyperkeratosis, responsive to corticoid therapy.

1.4 Posology and duration of treatment: 1 – 2 applications daily.

1.5 Pharmaceutical forms: ointment/cream.

1.6 Contraindications: bacterial, viral or fungal infections of the skin, skin cancer, acne or rosacea, nappy rash, inflammation or ulceration of varicoses; known hypersensitivity to flumetasone or to the other component. Not on large skin lesions. Not for children < 2 years.

1.7 Relevant warnings: long-term continuous topical therapy should be avoided where possible, particularly in children, as adrenal suppression, with or without clinical features of Cushing's syndrome, can occur even without occlusion. In this situation, topical steroids should be discontinued gradually under medical supervision because of the risk of adrenal insufficiency.
Avoid contact with the eyes and mucous membranes. If irritation or sensitisation develops, treatment should be discontinued.
If concomitant skin infections are present or develop, an appropriate antifungal or antibacterial agent should be used.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): adverse reactions: continuous application without interruption may result in local atrophy of the skin, striae and superficial vascular dilation. Adverse reactions that have been reported with the use of topical corticosteroids include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation and allergic contact dermatitis. The following may occur more frequently with the use of occlusive dressings: maceration of the skin, secondary infection, skin atrophy, striae and miliaria. In addition, prolonged use of salicylic acid preparations may cause dermatitis.

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I					
AT	Not authorised					
BE	POM	Cutaneous	Available combination product: flumetasone 0.02% + salicylic acid 3%. Available pharmaceutical form: cream	0.02%		15 g
CZ	Not authorised					
ES	Withdrawn					
FR	I	Cutaneous	Dermatoses responsive to corticosteroid therapy Available combination product: flumetasone 0.02g + salicylic acid 3g. Warnings: do not use on large skin surfaces; do not use for long period of treatment	0.02%		15 g

HR	Not authorised					
IE	POM					
LV	I					
MK	Not authorised					
PL	I	Cutaneous	Inflammation of the skin, especially allergic, running with persistent itching or hyperkeratosis, responsive to corticosteroid therapy Available combination product: flumetasone 0.2mg + salicylic acid 30mg. Available pharmaceutical form: ointment. Warnings: do not use on large skin lesions; do not use in children < 2 years	0.02%		15 g
RO	Not authorised					
SI	I					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I

Criteria:
Therapeutic indications
Safety profile
Medical supervision

3.2 Paediatric use: not for children < 2 years.

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Triamcinolone

1.2 ATC Code: D07XB02 - Corticosteroids, other combinations; corticosteroids, moderately potent, other combinations

1.3 Therapeutic indications: triamcinolone/salicylic acid: symptomatic treatment of steroid-responsive dermatoses with scaly keratotic component especially at the scalp in hairy areas and folds.

1.4 Posology and duration of treatment: 1 – 2 applications daily.

1.5 Pharmaceutical forms: cutaneous solution.

1.6 Contraindications: primary bacterial, viral and fungal diseases of the skin, acne, rosacea; known hypersensitivity to triamcinolone or to the other component.

1.7 Relevant warnings: long-term continuous topical therapy should be avoided where possible, particularly in infants and children, as adrenal suppression, with or without clinical features of Cushing's syndrome, can occur even without occlusion. In this situation, topical steroids should be discontinued gradually under medical supervision because of the risk of adrenal insufficiency. Avoid contact with the eyes and mucous membranes. If irritation or sensitisation develops treatment should be discontinued. If concomitant skin infections are present or develop, an appropriate antifungal or antibacterial agent should be used.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): adverse reactions: continuous application without interruption may result in local atrophy of the skin, striae and superficial vascular dilation. Adverse reactions that have been reported with the use of topical corticosteroids include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation and allergic contact dermatitis. The following may occur more frequently with the use of occlusive dressings: maceration of the skin, secondary infection, skin atrophy, striae and miliaria. In addition, prolonged use of salicylic acid preparations may cause dermatitis.

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I					
AT	I					
CZ	I					
ES	POM					
FR	I					
HR	Not authorised					
MK	Not authorised					
PL	Not authorised					
RO	I					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I

Criteria:
Therapeutic indications
Safety profile
Medical supervision needed

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Fluprednidene

1.2 ATC Code: D07XB03 - Corticosteroids, other combinations; corticosteroids, moderately potent, other combinations

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I					
AT	I					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
MK	Not authorised					
PL	Not authorised					
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Fluorometholone

1.2 ATC Code: D07XB04 - Corticosteroids, other combinations; corticosteroids, moderately potent, other combinations

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	POM					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
MK	Not authorised					
PL	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Dexamethasone

1.2 ATC Code: D07XB05 - Corticosteroids, other combinations; corticosteroids, moderately potent, other combinations

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	I					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
MK	Not authorised					
PL	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Combinations of corticosteroids

1.2 ATC Code: D07XB30 - Corticosteroids, other combinations; corticosteroids, moderately potent, other combinations

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	I					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
MK	Not authorised					
PL	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Betamethasone

1.2 ATC Code: D07XC01 - Corticosteroids, other combinations; corticosteroids, potent, other combinations

1.3 Therapeutic indications: *betamethasone/salicylic acid:* treatment of hyperkeratotic and dry corticosteroid-responsive dermatoses where the cornified epithelium may resist penetration of the steroid. The salicylic acid, as a result of its descaling action, allows access of the dermis more rapidly than by applying steroid alone.

1.4 Posology and duration of treatment: *Adults:* once to twice daily. In most cases a thin film should be applied to cover the affected area twice daily. For some patients adequate maintenance therapy may be achieved with less frequent application. It is recommended that preparations containing betamethasone/salicylic acid are prescribed for two weeks, and that treatment is reviewed at that time. The maximum weekly dose should not exceed 60g.
Children: dosage in children should be limited to 5 days.

1.5 Pharmaceutical forms: cream/ointment/cutaneous solution.

1.6 Contraindications: rosacea, acne, perioral dermatitis, perianal and genital pruritus; hypersensitivity to betamethasone or to salicylic acid; tuberculous and most viral lesions of the skin, particularly herpes simplex, vaccinia, varicella. In napkin eruptions, fungal or bacterial skin infections without suitable concomitant anti-infective therapy.

1.7 Relevant warnings: occlusion must not be used, since under these circumstances the keratolytic action of salicylic acid may lead to enhanced absorption of the steroid. Local and systemic toxicity is common, especially following long continuous use on large areas of damaged skin, in flexures or with polythene occlusion. If used in children or on the face, courses should be limited to 5 days. Long term continuous therapy should be avoided in all patients irrespective of age. Topical corticosteroids may be hazardous in psoriasis for a number of reasons, including rebound relapses following development of tolerance, risk of generalised pustular psoriasis and local systemic toxicity due to impaired barrier function of the skin. Careful patient supervision is important. Avoid contact with the eyes and mucous membranes. The systemic absorption of betamethasone dipropionate and salicylic acid may be increased if extensive body surface areas or skin folds are treated for prolonged periods or with excessive amounts of steroids. If irritation or sensitisation develops treatment should be discontinued. Any side effects that are reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children. If excessive dryness or increased skin irritation develops, discontinue use. Paediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and to exogenous corticosteroid effects than mature patients because of greater absorption due to a large skin surface area to body weight ratio. HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include a bulging fontanelle, headaches and bilateral papilledema.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): adverse reactions: continuous application without interruption may result in local atrophy of the skin, striae and superficial vascular dilation, particularly on the face. Adverse reactions that have been reported with the use of topical corticosteroids include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis and allergic contact dermatitis. The following may occur more frequently with the use of occlusive dressings: maceration of the skin, secondary infection, skin atrophy, striae and miliaria. In addition, prolonged use of salicylic acid preparations may cause dermatitis.

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	I					
BE	I	Cutaneous	Treatment of chronic psoriasis and other dermatoses (e.g. seborrhoeic dermatitis) Available combination product: betamethasone 0.5mg + calcipotriol 0.05mg	0.05%		15 mg
CZ	I	Cutaneous	Treatment of chronic inflammatory skin diseases Combination product containing 0.05% betamethasone	0.05%		
ES	POM					
FR	I	Cutaneous	Treatment of psoriasis vulgaris Available combination product: Betamethasone 0.5mg + calcipotriol 0.05mg. Warnings: do not use on large skin surfaces; do not use for long period of treatment	0.05%		
HR	I					
IE	Not authorised					
MK	Not authorised					
PL	I	Cutaneous	Available combination products: 1. Betamethasone 0.5mg + calcipotriol 0.05mg; 2. Betamethasone 0.5mg + clotrimazole 10mg; 3. Betamethasone 0.5mg + salicylic acid 30mg; 4. Betamethasone 0.5mg + gentamicin 1mg + clotrimazole 10mg. Available pharmac. forms: cream, gel and ointment. Warnings: do not use on facial skin, wounds, damaged skin, inflamed lesions in the anal or genital warts	0.05		MQP: Med.1: Ointment and gel: 30g; Med. 2: Cream: 15g; Med. 3: Ointment: 30g + Liquid: 50ml; Med. 4: Cream and ointment: 15g
RO	I					
SI	I					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I

Criteria:
Therapeutic indications
Safety profile

3.2 Paediatric use: dosage in children should be limited to 5 days.

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Desoximethasone

1.2 ATC Code: D07XC02 - Corticosteroids, other combinations; corticosteroids, potent, other combinations

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
MK	Not authorised					
PL	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Mometasone

1.2 ATC Code: D07XC03 - Corticosteroids, other combinations; corticosteroids, potent, other combinations

1.3 Therapeutic indications: initial treatment of inflammatory and pruritic manifestations of psoriasis moderate to severe (excluding widespread plaque psoriasis).

1.4 Posology and duration of treatment: *adults and children over 12 years of age:* a thin film of cream/ointment should be applied to the affected areas of skin once to twice daily.

1.5 Pharmaceutical forms: cream/ointment

1.6 Contraindications: facial rosacea, acne vulgaris, skin atrophy, perioral dermatitis, bacterial (e.g. impetigo, pyodermas), viral (e.g. herpes simplex, herpes zoster and chickenpox, verrucae vulgares, condylomata acuminata, molluscum contagiosum), parasitical and fungal (e.g. candida or dermatophyte) infections, varicella, tuberculosis, syphilis or post-vaccine reactions; hypersensitivity to mometasone furoate or to salicylic acid.

1.7 Relevant warnings: if irritation and/or sensitisation develop, treatment should be withdrawn and appropriate therapy instituted. Should an infection develop, use of an appropriate antifungal or antibacterial agent should be instituted. If a favourable response does not occur promptly, the corticosteroid should be discontinued until the infection is adequately controlled. Systemic absorption of topical corticosteriods can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycaemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment. Patients applying a topical steroid to a large surface area or areas under occlusion should be evaluated periodically for evidence of HPA axis suppression. As the safety and efficacy in paediatric patients below 12 years of age have not been established, its use in this age group is not recommended. It is not recommended for use on the face, flexures, genital or inguinal area. It should not be used under occlusion. It is not recommended for use in pustular or guttate psoriasis. Salicylic acid may act as a sunscreen. Topical steroids may be hazardous in psoriasis for a number of reasons including rebound relapses following development of tolerance, risk of centralised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin. If used in psoriasis careful patient supervision is important. As with all potent topical glucocorticoids, avoid sudden discontinuation of treatment. When long term topical treatment with potent glucocorticoids is stopped, a rebound phenomenon can develop which takes the form of a dermatitis with intense redness, stinging and burning. This can be prevented by slow reduction of the treatment, for instance, continue treatment on an intermittent basis before discontinuing treatment. Glucocorticoids can change the appearance of some lesions and make it difficult to establish an adequate diagnosis and can also delay the healing. Avoid contact with eyes, mucous membranes and open wounds.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance):

Adverse reactions:

Skin and subcutaneous tissue disorders
Common: pruritus, skin atrophy
Uncommon: skin striae, dermatitis acneiform,
Rare: skin hypopigmentation, hypertrichosis
Not known: skin dryness irritation, dermatitis, perioral dermatitis, maceration of the skin, miliaria and telangiectasiae.

General disorders and administration site conditions: Common: burning sensation.

Infections and infestations: Uncommon: infection

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	II					
AT	Not authorised					
BE	Not authorised					
CZ	I	Cutaneous	Moderate and severe psoriasis	0.1%		
ES	POM					
FR	Not authorised					
HR	I					
IE	Not authorised					
MK	Not authorised					
PL	I	Cutaneous	Indicated for removing plaque psoriasis in the initial treatment of moderate to severe psoriasis	0.1%		45 g
RO	I					
SE	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

References: List I

Criteria:
Therapeutic indications
Safety profile
Medical supervision

3.2 Paediatric use: as the safety and efficacy in paediatric patients below 12 years of age have not been established, its use in this age group is not recommended.

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Diflucortolone

1.2 ATC Code: D07XC04 - Corticosteroids, other combinations; corticosteroids, potent, other combinations

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
MK	Not authorised					
PL	I	Cutaneous	Initial treatment of superficial fungal infections of the skin with concomitant potent inflammatory or eczematous skin lesions	0.1%		15 g
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: –

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Corticosteroids, very potent, other combinations (no specific active ingredients are included in this sub-group)

1.2 ATC Code: D07XD - Corticosteroids, other combinations

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
ES	Not authorised					
FR	Not authorised					
HR	Not authorised					
IE	Not authorised					
MK	Not authorised					
PL	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Triamcinolone

1.2 ATC Code: H02AB08 - Corticosteroids for systemic use - plain, glucocorticoids

1.3 Therapeutic indications: *intra-articular use:* for alleviating the joint pain, swelling and stiffness associated with rheumatoid arthritis and osteoarthrosis with an inflammatory component. Also used for the treatment of bursitis, epicondylitis and tenosynovitis.
Intra-muscular use: where sustained systemic corticosteroid treatment is required: allergic states, e.g. bronchial asthma, seasonal or perennial allergic rhinitis; for seasonal allergies, patients who do not respond to conventional therapy may achieve remission of symptoms over the entire period with a single intra-muscular injection; endocrine disorders, e.g. primary or secondary adrenocortical insufficiency; collagen disorders, e.g. during exacerbation of maintenance therapy for selected cases of systemic lupus erythematosus (SLE) or acute rheumatic carditis; dermatological diseases, e.g. pemphigus, severe dermatitis and Stevens-Johnson syndrome; rheumatic, gastrointestinal or respiratory disorders (as an adjunctive, short-term therapy); haematological disorders, e.g. acquired (auto-immune) haemolytic anaemia; neoplastic diseases, e.g. palliative management of leukaemia and lymphomas; renal disease, such as acute interstitial nephritis, minimal change nephrotic syndrome or lupus nephritis.

1.4 Posology and duration of treatment: *intra-articular injection:* triamcinolone dosages may vary from 5 mg to 10 mg for smaller joints and up to 40 mg for larger joints, depending on the specific disease being treated. Single injections into several sites for multiple joint involvements, up to a total of 80 mg, have been given without undue reactions.
Intra-muscular injection: to avoid the danger of sub-cutaneous fat atrophy, it is important to ensure that deep intra-muscular injections are given into the gluteal site. The deltoid should not be used. Alternate sides should be used for subsequent injections.
Adults and children over 12 years: the suggested initial dose is 40 mg injected deeply into the upper, outer quadrant of the gluteal muscle. Subsequent dosage depends on the patient's response and period of relief. Patients with hay fever or pollen asthma who do not respond to conventional therapy may obtain remission of symptoms that last for the duration of the pollen season following a single dose of 40-100 mg given when allergic symptoms appear.
Elderly: treatment of elderly patients, particularly over the long-term, should be planned, bearing in mind the more serious consequences of the common side-effects of corticosteroids in old age, especially osteoporosis, diabetes, hypertension, susceptibility to infection and thinning of the skin. Close clinical supervision is required to avoid life-threatening reactions.
Children from 6-12 years of age: the suggested initial dose of 40 mg injected deeply into the gluteal muscle should be scaled according to the severity of symptoms and the age and weight of the child.
Triamcinolone withdrawal: in patients who have received more than physiological doses of triamcinolone, withdrawal should not be abrupt. The dose should be reduced and the dosage interval increased until a dose of not more than 40 mg and a dosage interval of at least three weeks have been achieved, as the dose of systemic corticosteroid is reduced. Clinical assessment of disease activity may be needed. Abrupt withdrawal of short-term systemic corticosteroid treatment is appropriate if it is considered that the disease is unlikely to relapse. A single dose, which is not repeated within a three week period, is unlikely to lead to clinically-relevant HPA axis suppression in the majority of patients. However, gradual withdrawal of systemic corticosteroid therapy should always be considered in the following patient groups: patients who have had repeated courses of systemic corticosteroids (when a course of triamcinolone has been prescribed within one year of cessation of long-term therapy (months or years)); patients who may have adrenocortical insufficiency due to reasons other than exogenous corticosteroid therapy.

1.5 Pharmaceutical forms: suspension for injection.

1.6 Contraindications: hypersensitivity to triamcinolone; systemic infections unless specific anti-infective therapy is employed.

1.7 Relevant warnings: *intra-articular injection*: corticosteroids should not be injected into unstable joints. Patients should be specifically warned to avoid over-use of the joints in which symptomatic relief may have been obtained. Severe joint destruction with necrosis of bone may occur if repeated intra-articular injections are given over a long period of time. Care should be taken if injections are given into tendon sheaths to

avoid injection into the tendon itself. Repeated injection into inflamed tendons should be avoided as it has been shown to cause tendon rupture. Due to the absence of a true tendon sheath, the Achilles tendon should not be injected with depot corticosteroids. Intra-articular injections should not be carried out in the presence of active infection in or near the joints. The preparation should not be used to alleviate joint pain arising from infectious states such as gonococcal or tubercular arthritis.

Intra-muscular injection: during prolonged therapy, a liberal protein intake is essential to counteract the tendency towards gradual weight loss that is sometimes associated with a negative nitrogen balance and wasting of skeletal muscle. Undesirable effects may be minimised by using the lowest effective dose for the minimum period and by administering the daily requirement as a single morning dose on alternate days whenever possible. Frequent patient reviews are required in order to titrate the dose appropriately against disease activity. Adrenal cortical atrophy develops during prolonged therapy and may persist for years after stopping treatment. Withdrawal of corticosteroids after prolonged therapy must, therefore, always be gradual to avoid acute adrenal insufficiency and should be tapered off over weeks or months according to the dose and duration of treatment. During prolonged therapy, any intercurrent illness, trauma or surgical procedure will require a temporary increase in dosage. If corticosteroid use has been stopped following prolonged therapy, it may need to be reintroduced temporarily. Patients should carry steroid treatment cards, which give clear guidance on the precautions to be taken to minimise risk and which provide details of the prescriber, drug, dosage and the duration of treatment. Suppression of the inflammatory response and immune function increases the susceptibility to infections and their severity. The clinical presentation may often be atypical and serious infections, such as septicaemia and tuberculosis, may be masked and may reach an advanced stage before being recognised. Chickenpox and measles are of particular concern since these normally minor illnesses may be fatal in immuno-suppressed patients. Unless they have already had chickenpox, patients receiving parenteral corticosteroids for purposes other than replacement should be regarded as being at risk of severe chickenpox. Manifestations of fulminant illness include pneumonia, hepatitis and disseminated intra-vascular coagulation; rash is not necessarily a prominent feature. Exposed non-immune patients who are receiving systemic corticosteroids or who have used them within the previous 3 months require passive immunisation with varicella zoster immunoglobulin (VZIG); varicella-zoster immunoglobulin should preferably be given within 3 days of exposure and not later than 10 days. Confirmed chickenpox warrants specialist care and urgent treatment. Corticosteroids should not be stopped and the dose may need to be increased. Patients should be advised to avoid exposure to measles and to seek medical advice without delay if exposure occurs. Prophylaxis with normal immunoglobulin may be needed.

During corticosteroid therapy, the antibody response is reduced and this can affect the patient's response to vaccines. Live vaccines should not be administered. Patients and/or carers should be warned that potentially severe psychiatric adverse reactions may occur with systemic steroids. Symptoms typically emerge within a few days or weeks of starting the treatment. Risks may be higher with high dosages/systemic exposure; although dosage levels do not allow prediction of the onset, type, severity or duration of reactions. Recovery from such adverse reactions can be achieved either by dose reduction or withdrawal; although specific treatment may be necessary. Patients/carers should be encouraged to seek medical advice if worrying psychological symptoms develop, especially if depression or suicidal ideation is suspected. Patients/carers should also be alert to possible psychiatric disturbances that may occur either during or immediately after dose tapering/withdrawal of systemic steroids; although such reactions have been infrequently reported. Particular care is required when considering the use of systemic corticosteroids in patients who they themselves (or their first degree relatives) have an existing or previous history of severe affective disorders (such as depressive or manic-depressive illnesses and previous steroid psychosis).

Special precautions: particular care is required when considering the use of systemic corticosteroids in patients with the following conditions (frequent patient monitoring is necessary): recent intestinal anastomoses, diverticulitis, thrombophlebitis, existing or previous history of severe affective disorders (especially previous steroid psychosis), exanthematous disease, chronic nephritis or renal insufficiency, metastatic carcinoma, osteoporosis (post-menopausal females are particularly at risk); patients with an active peptic ulcer (or a history of peptic ulcer); myasthenia gravis; latent or healed tuberculosis; in the presence of local or systemic viral infection, systemic fungal infections or in active infections not controlled by antibiotics; acute psychoses; acute glomerulonephritis; hypertension; congestive heart failure; glaucoma (or a family history of glaucoma); previous steroid myopathy or epilepsy; liver failure.

Corticosteroid effects may be enhanced in patients with hypothyroidism or cirrhosis and decreased in hyperthyroid patients. Diabetes may be aggravated, necessitating a higher insulin dosage. Latent diabetes mellitus may be precipitated. Menstrual irregularities may occur, and this possibility should be mentioned to female patients. Rare instances of anaphylactoid reactions have occurred in patients receiving corticosteroids, especially when a patient has a history of drug allergies. All corticosteroids increase

calcium excretion.
Use in children: triamcinolone 40 mg/ml is not recommended for children under six years of age. Corticosteroids cause dose-related growth retardation in infancy, childhood and adolescence that may be irreversible, so growth and development of children on prolonged corticosteroid therapy should be carefully observed.
Use in elderly: the common adverse effects of systemic corticosteroids may be associated with more serious consequences in old age, especially osteoporosis, hypertension, hypokalaemia, diabetes, susceptibility to infection and thinning of the skin. Close clinical supervision is required to avoid life-threatening reactions.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): *adverse reactions:* where adverse reactions occur they are usually reversible on cessation of therapy. The incidence of predictable side-effects, including HPA axis suppression, correlates with the relative potency of the drug, dosage, timing of administration and duration of treatment. Absorption of triamcinolone following injection by the intra-articular route is rare. However, patients should be closely watched for the following adverse reactions that may be associated with any corticosteroid therapy:
Anti-inflammatory and immuno-suppressive effects: increased susceptibility and severity of infections with suppression of clinical symptoms and signs, opportunistic infections, recurrence of dormant tuberculosis.
Fluid and electrolyte disturbances: sodium retention, fluid retention, congestive heart failure in susceptible patients, potassium loss, cardiac arrhythmias or ECG changes due to potassium deficiency, hypokalaemic alkalosis, increased calcium excretion and hypertension. Musculoskeletal: muscle weakness, fatigue, steroid myopathy, loss of muscle mass, osteoporosis, avascular osteonecrosis, vertebral compression fractures, delayed healing of fractures, aseptic necrosis of femoral and humeral heads, pathological fractures of long bones and spontaneous fractures, tendon rupture.
Hypersensitivity: anaphylactoid reaction, anaphylaxis including anaphylactic reactions and anaphylactic shock, angiodema, rash, pruritus and urticaria (particularly where there is a history of drug allergies).
Dermatological: impaired wound healing, thin fragile skin, petechiae and ecchymoses, facial erythema, increased sweating, purpura, striae, hirsutism, acneiform eruptions, lupus erythematous-like lesions and suppressed reactions to skin tests.
Gastrointestinal: dyspepsia, peptic ulcer (with possible subsequent perforation and haemorrhage), pancreatitis, abdominal distension and ulcerative oesophagitis, candidiasis.
Neurological: euphoria, psychological dependence, depression, insomnia, convulsions, increased intra-cranial pressure with papilloedema (pseudo-tumour cerebri) usually after treatment, vertigo, headache, neuritis or paraesthesias and aggravation of pre-existing psychiatric conditions and epilepsy. A wide range of psychiatric reactions have been reported including affective disorders (such as irritable, euphoric, depressed and labile moods and suicidal thoughts), psychotic reactions (including mania, delusions, hallucinations and aggravation of schizophrenia), behavioural disturbances, irritability, anxiety, sleep disturbances and cognitive dysfunction (including confusion and amnesia). Such reactions are common and may occur in both adults and children. In adults, the frequency of severe psychiatric reactions has been estimated to be 5-6%. Psychological effects have been reported on withdrawal of corticosteroids; the frequency is unknown.
Endocrine: menstrual irregularities and amenorrhoea; development of the Cushingoid state; suppression of growth in childhood and adolescence; secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress (e.g. trauma, surgery or illness); decreased carbohydrate tolerance; manifestations of latent diabetes mellitus and increased requirements for insulin or oral hypoglycaemic agents in diabetes; weight gain; negative protein and calcium balance; increased appetite.
Ophthalmic: posterior sub-capsular cataracts, increased intra-ocular pressure, glaucoma, exophthalmos, papilloedema, corneal or scleral thinning, exacerbation of ophthalmic viral or fungal diseases.
Others: necrotising vasculitis, thrombophlebitis, thromboembolism, leucocytosis, insomnia and syncopal episodes.
Withdrawal symptoms and signs: fever, myalgia, arthralgia, rhinitis, conjunctivitis, painful itchy skin nodules and weight loss may occur on withdrawal of treatment. Too rapid a reduction in dose following prolonged treatment can lead to acute adrenal insufficiency, hypotension and death.
Intra-articular injection: reactions following intra-articular administration have been rare. In a few instances, transient flushing and dizziness have occurred. Local symptoms such as post-injection flare, transient pain, irritation, sterile abscesses, hyper- or hypo-pigmentation, Charcot-like arthropathy and an occasional increase in joint discomfort may occur. Local fat atrophy may occur if the injection is not given into the joint

space, but this is temporary and disappears within a few weeks to months.
Intra-muscular injection: Severe pain has been reported following intra-muscular administration. Sterile abscesses, cutaneous and sub-cutaneous atrophy, hyper-pigmentation, hypo-pigmentation and Charcot-like arthropathy have also occurred.

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	I					
AT	I (1)					
BE	I					
CH	II					
CZ	I					
DE	I + exemption Annex III					
ES	POM					
FR	I					
HR	I					
HU	II					
IE	II					
IT	II					
LT	II					
MK	I					
NL	POM					
NO	II					
PL	I					
RO	Not authorised					
SI	II					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List I

Criteria: treatment should be carried out under the supervision of a physician.

3.2 Paediatric use: not recommended for children under six years of age.

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Triamcinolone

1.2 ATC Code: R01AD11 - Decongestants and other nasal preparations for topical use, corticosteroids

1.3 Therapeutic indications: treatment of symptoms of seasonal and perennial allergic rhinitis.

1.4 Posology and duration of treatment: *patients aged 12 years and over:* the recommended starting dose is 220 µg as 2 sprays in each nostril once daily. Once symptoms are under control, patients can be maintained on 110 µg (1 spray in each nostril, once daily).
Paediatric patients aged 6 to 12 years: the recommended dose is 110 µg as 1 spray in each nostril once daily. In patients with more severe symptoms, a dose of 220 µg may be used, but, once symptoms are under control, patients should be maintained on the lowest effective dose. Until further evidence is available, continuous use beyond 3 months in children under 12 years of age is not recommended.

1.5 Pharmaceutical forms: nasal spray suspension.

1.6 Contraindications: hypersensitivity to triamcinolone or an infection in the nose.

1.7 Relevant warnings: if there is any reason to suppose that adrenal function is impaired, care must be taken if transferring patients from systemic steroid treatment to topical treatment with triamcinolone.
In clinical studies of intra-nasally administered triamcinolone, development of localised infections of the nose and pharynx with *Candida albicans* has occurred infrequently. When such an infection develops, it may require treatment with appropriate local therapy and discontinuation of treatment with intra-nasal triamcinolone.
Because of the inhibitory effect of corticosteroids on wound healing, patients who have had recent nasal surgery or recent prolonged nose-bleeds or any other nasal problems should consult their doctor before using products containing intra-nasally administered triamcinolone.
Systemic effects of nasal corticosteroids may occur, particularly if high doses are prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids and may vary in individual patients and between different corticosteroid preparations. Potential systemic effects may include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, cataracts, glaucoma and, more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children).
Treatment with higher than recommended doses may result in clinically-significant adrenal suppression. If there is evidence of using higher than recommended doses, then additional systemic corticosteroid cover should be considered during periods of stress or elective surgery.
As experience with intra-nasally administered triamcinolone in children under 6 years of age is limited, use in this age group is not recommended.
Reduction in growth velocity has been reported in children receiving nasal corticosteroids at licensed doses.
It is recommended that the height of children receiving prolonged treatment with nasal corticosteroids is regularly monitored. If growth is slowed, therapy should be reviewed with the aim of reducing the dose of nasal corticosteroid, if possible, to the lowest dose at which effective control of symptoms is maintained. In addition, consideration should be given to referring the patient to a paediatric specialist. The long-term effects of reduction in growth velocity associated with nasal corticosteroids, including the impact on final adult height are unknown.
Glaucoma and/or cataracts have been reported in patients receiving nasal corticosteroids. Therefore, close monitoring is warranted in patients with a change in vision or with a history of increased intra-ocular pressure, glaucoma and/or cataracts.

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): the most frequently reported adverse reactions in adults are:
Infections and infestations: flu syndrome, pharyngitis, rhinitis (all common).
Immune system disorders: hypersensitivity (including rash, urticaria, pruritus and facial oedema).
Psychiatric disorders: insomnia.

Nervous system disorders: headache (common); dizziness and alterations of taste and smell.
Eye disorders: cataracts, glaucoma, increased ocular pressure.
Respiratory, thoracic and mediastinal disorders: bronchitis, epistaxis, cough (all common); nasal septum perforations (rare); nasal irritation; dry mucous membrane; nasal congestion; sneezing; dyspnoea.
Gastrointestinal disorders: dyspepsia and tooth disorder (common); nausea.
G*eneral disorders and administration site conditions*: fatigue.
Testing: decreased blood cortisol.

Systemic effects of nasal corticosteroids may occur, particularly when prescribed at high doses for prolonged periods.

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	II					
AT	I (1)					
BE	Not authorised					
CH	II + exemption Annex III	Nasal	Age >18 years; for max. 3 months			16.50mg
CZ	Not authorised					
FR	I					
FI	II + exemption Annex III	Nasal		55 µg		16.65mg
HR	II					
IE	II					
IT	II					
MK	Not authorised					
NL	POM					
PL	Not authorised					
PT	POM					
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: List II

Criteria:
Therapeutic indications
Treatment does not require frequent clinical examination

3.2 Paediatric use: as experience with intra-nasally administered triamcinolone in children under 6 years of age is limited, use in this age group is not recommended. Until further evidence is available, continuous use beyond 3 months in children under 12 years of age is not recommended.

4. COMMENTS/REFERENCES

References:

Martindale: The Complete Drug Reference, 37th edition
eMC (Available at: http://www.medicines.org.uk/emc/)
PDR online 2012 (Available at: http://www.pdr.net/)

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Triamcinolone

1.2 ATC Code: R03BA06 - Other drugs for obstructive airway diseases, inhalants, glucocorticoids

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions: no data in *Melclass* database.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Triamcinolone

1.2 ATC Code: S01BA05 - Anti-inflammatory agents, corticosteroids - plain

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

.

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions:

Country	Prescription status	Additional details / Exemptions				
		Routes of administration	Comments	MS	MDD	MQP
Melclass database*	-					
AT	Not authorised					
BE	Not authorised					
CZ	Not authorised					
DE	Currently not available					
FR	I					
HR	Not authorised					
IT	Not authorised					
MK	Not authorised					
PL	Not authorised					
PT	POM					
RO	Not authorised					

* Melclass database - Available at: http://www.edqm.eu/melclass/

No data available from other member states.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

1. THERAPEUTIC PROFILE

1.1 Active ingredient: Triamcinolone and anti-infectives

1.2 ATC Code: S02CA04 - Corticosteroids and anti-infectives in combination, corticosteroids and anti-infectives in combination

1.3 Therapeutic indications: -

1.4 Posology and duration of treatment: -

1.5 Pharmaceutical forms: -

1.6 Contraindications: -

1.7 Relevant warnings: -

2. LIST DIRECT/INDIRECT RISKS (SAFETY PROFILE)

2.1 Direct risks (Pharmacovigilance): -

2.1.1 Recent cases at European level: -

2.1.2 Indirect risks (incorrect use): -

3. CONCLUSIONS – RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Member states' legal classification of the active ingredient for these therapeutic indications (ATC codes) and supply conditions: no data in *Melclass* database.

3.1 Conditions of supply (Indications, Administration Route, MS, MDD, MQP, as applicable):

Recommendation: not to classify

3.2 Paediatric use: -

4. COMMENTS/REFERENCES

References: -

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