

In line with the [updated advice from WHO](#), neither the PaedF working party nor the EDQM recommend the use of the below listed drugs outside their authorised indications for experimental treatment of COVID-19. The prescriber remains responsible to make an individual assessment of risks and benefits for each patient. The [European Medicines Agency](#) also advises to only use the below listed drugs for their authorised indications or within clinical trials or emergency use programmes in hospitalised patients.

Product	Strength	How to Formulate	Excipients†	Comments
<b>Hydroxychloroquine sulfate</b>				
<p><b>Expert opinion for extemporaneous preparation:</b> Hydroxychloroquine sulfate is a highly soluble drug. It is expected that manipulation of the formulation will have minimal impact on bioavailability. However, the presence of high amounts of sugar alcohols (such as sorbitol and xylitol) in an oral liquid might affect bioavailability (<a href="#">Ruiz-Ojeda FJ, Plaza-Díaz J, Sáez-Lara MJ, et al. Adv Nutr 2019;10(1):S31-48</a>). Hydroxychloroquine has a bitter taste (<a href="#">Blaschek W, Ebel S, Hackenthal E, et al. Hagers Enzyklopädie der Arzneistoffe und Drogen. Stuttgart, Germany: Wissenschaftliche Verlagsgesellschaft; 2007</a>).</p> <p>The extemporaneously prepared oral liquids described in literature show that tablets can be processed in various aqueous bases. When the described commercialized bases are unavailable it is expected that every aqueous base can be used. Removing the film-coating is usually not necessary before crushing the tablets, but it may ease the crushing and further processing.</p> <p>The tablets can be crushed to be used in capsules delivering the right dose. Using a mortar to crush the tablets might result in some loss of the API (<a href="#">Oralia.nl</a>).</p> <p>Caution: when manipulating tablets, be aware of the moiety (129 mg hydroxychloroquine sulfate equals 100 mg hydroxychloroquine base).</p>				
<b>Tablets</b>				
Plaquenil 200 mg film-coated tablets (Sanofi, EU), Quensyl 200 mg film-coated tablets (Sanofi, DE)	200 mg Hydroxychloroquine sulfate, eq. to 155 mg Hydroxychloroquine (base)	---	Maize starch lactose monohydrate povidone magnesium stearate hypromellose macrogol 4000 titanium dioxide	
Xanban (Aristo, ES) / Hydroxychloroquin 200 mg film-coated tablets (Aristo, DE, PT; axcount, DE, UK; Cf, NL; DOC Generici, IT, NL; Dr. Eberth, DE; Teva/ratiopharm, DE, NL, ES) / Hidroxicloroquina (Basi, PT) / Quinoric (Bristol, CY, UK)	200 mg Hydroxychloroquine sulfate, eq. to 155 mg Hydroxychloroquine (base)		Maize starch calcium hydrogenphosphate dihydrate colloidal anhydrous silica polysorbate 80 talc magnesium stearate hypromellose macrogol 6000 titanium dioxide	
Dolquine film coated tablet (Product Science Technology, ES)	200 mg Hydroxychloroquine sulfate, eq. to 155 mg Hydroxychloroquine (base)	---	Microcrystalline cellulose calcium hydrogenphosphate crospovidon magnesium stearate hypromellose macrogol 6000 titanium dioxide	

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Tablets (continued)				
Hydroxychloroquine 200 mg film-coated tablets (Blackrock, UK)	200 mg Hydroxychloroquine sulfate, eq. to 155 mg Hydroxychloroquine (base)	---	<b>Maize starch</b> <b>lactose monohydrate</b> croscarmellose sodium hypromellose magnesium stearate talc macrogol 6000 <b>polysorbate 80</b> <b>titanium dioxide</b> yellow iron oxide	
Ercoquin film-coated tablet (Meda, DK)	250 mg Hydroxychloroquine sulphate, eq. to 194 mg Hydroxychloroquine (base)	---	<b>Maize starch</b> <b>lactose monohydrate</b> microcrystalline cellulose povidone silica magnesium stearate talc hypromellose glycerol <b>polysorbate 80</b> macrogol 6000 <b>titanium dioxide</b> sucrose methyl parahydroxybenzoate <b>propyl</b> <b>parahydroxybenzoate</b> iron oxide	
Hydroxychloroquine 300 mg film-coated tablets (Blackrock, UK)	300 mg Hydroxychloroquine sulfate, eq. to 233 mg Hydroxychloroquine (base)	---	<b>Maize starch</b> <b>lactose monohydrate</b> croscarmellose sodium hypromellose magnesium stearate talc macrogol 6000 <b>polysorbate 80</b> <b>titanium dioxide</b>	
Plaquinol 400 mg (Alfasigma, PT)	400 mg Hydroxychloroquine sulfate, eq. to 310 mg Hydroxychloroquine (base)	---	<b>Maize starch</b> calcium hydrogenphosphate dihydrate magnesium stearate <b>tartrazine (E102)</b>	

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<b>Oral suspension</b>				
Extemporaneous preparation ( <a href="#">Nahata MC, Pai VB. Pediatric Drug Formulations. 7th Edition; Pesko LJ. Am Druggist 1993;207(4):57</a> )	25 mg/mL Hydroxychloroquine sulphate, eq. to 19.35 mg/mL Hydroxychloroquine (base)	Remove film-coating from 15x 200 mg coated tablets and comminute tablet cores; add 15 mL Ora-Plus and levigate to a fine paste. Add the remaining 45 mL Ora-Plus, rinse the mortar with water for irrigation and mix to 120 mL; fill into amber glass bottles.	200 mg coated tablets + OraPlus* 60 mL, Sterile water for irrigation NF q.s. up to 120 mL	Storage: up to 30 days in amber glass bottle; store in fridge (poor justification by data), no data on microbiological stability
Extemporaneous preparation ( <a href="#">McHenry AR, Wempe MF, Rice PJ. Int J Pharm Compd 2017;21(3):251-4; Allen Loyd V Jr. Int J Pharm Compd 2017;21(6):494</a> )	25 mg/mL Hydroxychloroquine sulphate, eq. to 19.35 mg/mL Hydroxychloroquine (base)	Crush Plaquenil 200 mg tablets into fine powder. Mix with small quantities of Oral Mix* or Oral Mix SF* to form a smooth paste. Add additional Oral Mix* or Oral Mix SF* geometrically to final volume and mix well.	200 mg coated tablets + Oral Mix* : Oral Mix SF* 1:1 (Medisca)	Storage: up to 16 weeks in amber plastic bottle at 4 °C and 25 °C, no data on microbiological stability
<b>Oral solution</b>				
Extemporaneous preparation ( <a href="#">Formulário Galénico Português (FGP): 2007, Publicações Farmácia Portuguesa. ANF, 2008</a> )	15 mg/mL Hydroxychloroquine sulfate, eq. to 11.61 mg/mL Hydroxychloroquine (base)	Dissolve 1.5 g hydroxychloroquine sulphate in 20 mL purified water and mix. Add FGP B.12 vehicle* and mix well by stirring (manually or mechanically with 500 rpm for 10 sec). Adjust the pH to 4-6 with 25% citric acid solution or 25% sodium citrate solution. Fill up to the target value (100 mL) with FGP B.12 vehicle* and mix well.	Citric acid sodium citrate FGP B.12 vehicle*	Storage: up to 1 month in amber glass bottle at 2 – 8 °C  Contains propylparaben. It may also be preserved with sodium benzoate or potassium sorbate at 0.2 % (m/V).

API=active pharmaceutical ingredient. BCS=biopharmaceutica classification system

†Excipients raising concern for children in bold

\*Oral Mix: Purified Water, sucrose, glycerol, **sorbitol**, cherry flavour, microcrystalline cellulose, carmellose, sodium xanthan gum, **κ-carrageenan**, sodium citrate, citric acid, potassium sorbate, methylparaben, **simethicone**

Oral Mix SF: Purified Water, glycerol, **sorbitol**, cherry flavour, microcrystalline cellulose, carmellose, **sodium saccharin**, sodium xanthan gum, **κ-carrageenan**, sodium citrate, citric acid, potassium sorbate, methylparaben, **propylparaben**, **simethicone**

OraPlus: Purified water, microcrystalline cellulose, carmellose, xanthan gum, **κ-carrageenan**, calcium sulfate, trisodium phosphate, citric acid, sodium phosphate, **dimethicone**, methylparaben, potassium sorbate

FGP B.12 vehicle: Contains methylparaben, **propylparaben**, propylene glycol, sucrose, banana essence and methylcellulose

#### Not Marketed

Duplaxil by Laboratorios Gebro Pharma (ES), contains 400 mg sulfate salt eq. to 310 mg hydroxychloroquine (base); **maize starch**, calcium hydrogen phosphate, povidone, magnesium stearate, Opadry II coating (polyvinyl alcohol based)

Hydroxychloroquine sulfate by Aristo Pharma Iberia, SL (PT), contains 200 mg of hydroxychloroquine sulphate; **maize starch**, calcium hydrogen phosphate di-hydrate, anhydrous colloidal silica, **polysorbate 80**, talc, magnesium stearate, hypromellose, macrogol 6000, **titanium dioxide** (E171)

Hydroxychloroquine sulfate by Laboratórios Basi - Indústria Farmacêutica, S.A (PT), contains 200 mg of hydroxychloroquine sulphate; **maize starch**, calcium hydrogen phosphate di-hydrate, anhydrous colloidal silica, **polysorbate 80**, talc, magnesium stearate, hypromellose, macrogol, **titanium dioxide** (E171), purified water

No proven evidence on efficacy and safety in treating COVID-19