

Comments

Neither the PaedF working party nor the EDQM make any recommendation to use the below listed drugs for experimental treatment of COVID-19. Available knowledge is limited. The prescriber remains responsible to make an individual assessment of risks and benefits for each patient. Although great care has been taken in compiling and checking the information contained in this table, neither the PaedF working party nor the EDQM is liable for any mistakes, incompleteness or inaccuracies.

How to Formulate

Strength†

Product

Excipients‡

Dexamethasone					
Expert opinion for extemporaneous preparation: dexamethasone is a highly soluble drug (BCS class I (<i>Plöger GF, Hofsäss MA, Dressman JB. J Pharm Sci 2018;107(6):1478-88</i>)). A number of oral solutions are marketed in selected countries. Available authorised tablet formulations are uncoated and may be crushed and used in case none of the licensed products or pure active substance would be available. It is expected that manipulation of the formulation will have a minimal impact on bioavailability. Safety precautions: when manipulating tablets, it is advised to take adequate measures to prevent inhalation and dermal exposure of the potentially harmful active substance.					
Oral solution					
Infectodexakrupp 2 mg/5 mL (Infectopharm, AT, DE)	Each 5 mL contains 2 mg dexamethasone (as dexamethasone dihydrogen phosphate disodium), 450 mg propylene glycol, 1375 mg liquid maltitol and 700 mg liquid sorbitol		Spearmint flavour (containing safrol) Maltitol solution Benzoic acid Purified water Sodium citrate Citric acid monohydrate Propylene glycol Liquid sorbitol (non-		
Dexsol 2 mg/5 mL Oral Solution (Rosemont, IE, SE, UK)	Each 5 mL contains 2 mg dexamethasone (as dexamethasone sodium phosphate), 450 mg propylene glycol, Garden mint flavour (containing 0.61 mg propylene glycol), 1375 mg liquid maltitol and 700 mg liquid sorbitol		crystallising) Benzoic acid Propylene glycol Citric acid monohydrate Liquid maltitol Garden mint flavour (containing isopropanol and propylene glycol) Liquid sorbitol (non- crystallising) Sodium citrate Purified water		
Dexamethasone 2 mg/5 mL Oral solution (Focus, SE, UK)	Each 5 mL contains 2 mg of dexamethasone (as dexamethasone sodium phosphate), 450 mg propylene glycol, 1375 mg liquid maltitol, 700 mg liquid sorbitol (noncrystallising) and 5 mg benzoic acid		Benzoic acid Propylene glycol Citric acid monohydrate Liquid maltitol Liquid sorbitol (non- crystallising) Sodium citrate dihydrate Mint flavour Purified water		

16 October 2020 Page **1** of **6**



Product	Strength†	How to Formulate	Excipients‡	Comments
Oral solution (continued)			
Martapan 2 mg/5 mL	Each 5 mL contains 2 mg		Benzoic acid	
Oral solution	dexamethasone (as		Propylene glycol	
(Martindale, UK)	dexamethasone sodium		Citric acid	
	phosphate), 0.061 mmol		monohydrate	
	of sodium, 0.6 g of		Liquid maltitol	
	liquid sorbitol, 1.4 g of		Garden mint flavour	
	liquid maltitol, 0.5 g of		(contains propylene	
	propylene glycol and		glycol)	
	0.005 g of benzoic acid		Liquid sorbitol (non-	
			crystallising)	
			Sodium citrate	
			Purified water	
			Citric acid	
Dexamethasone	Each 5 mL contains 2 mg		Propylene glycol	
2 mg/5 mL Oral	dexamethasone (as		Benzoic acid	
solution (Syri, UK)	dexamethasone sodium		Citric acid	
	phosphate), 182.2 mg		monohydrate	
	propylene glycol,		Sodium citrate	
	1375 mg liquid maltitol,		Liquid maltitol	
	3 mg benzoic acid and		Liquid sorbitol (non-	
	700 mg liquid sorbitol		crystallising)	
			Garden mint flavour	
			(containing propylene	
			glycol)	
			Purified water	
Dexamethasone	Each 5 mL contains 2 mg		Benzoic acid	
2 mg/5 mL Oral	dexamethasone (as		Propylene glycol	
solution (Wockhardt,	dexamethasone sodium		Citric acid	
UK)	Phosphate), 1.75 g		monohydrate	
	maltitol, 500 mg		Sodium citrate	
	sorbitol, 470 mg		Maltitol liquid	
	propylene glycol and		Liquid sorbitol (non-	
	approx 7.6 mg ethanol		crystallising)	
			Garden mint flavour	
			Ethanol	
			Hydrochloric acid	
			Sodium hydroxide	
			Purified water	
Dexamethasone	Each 5 mL contains		Propylene glycol	
10 mg/5 mL Oral	10 mg dexamethasone		Benzoic acid	
solution (Rosemont,	(as dexamethasone		Citric acid	
IE, SE, UK)	sodium phosphate),		monohydrate	
	1375 mg liquid maltitol		Sodium citrate	
	and 700 mg sorbitol		Liquid maltitol	
	liquid (non-crystallising)		Liquid sorbitol (non-	
			crystallising)	
			Purified water	

16 October 2020 Page **2** of **6**



Product	Strength†	How to Formulate	Excipients‡	Comments
Oral solution (continued)			
Dexamethasone	Each 5 mL contains		Propylene glycol	
10 mg/5 mL and	10 mg / 20 mg		Liquid maltitol	
20 mg/5 mL Oral	dexamethasone (as		Mint flavour	
solution (Synchrony,	dexamethasone sodium		Liquid sorbitol (non-	
UK)	phosphate), 1375 mg/		crystallising)	
- /	1375 mg liquid maltitol		Sodium citrate	
	and 700 mg / 700 mg		dihydrate	
	sorbitol		Disodium edetate	
	!		Sucralose	
			Sodium hydroxide	
	!		solution 1N	
	!		Purified water	
Dexliq 4 mg/mL	Each 5 mL contains		Propylene glycol	
(Laboratoires CTRS,	20 mg dexamethasone		Liquid maltitol	
CZ, DK, FR, IS, LU, SK)	(as dexamethasone		Mint flavour	
	sodium phosphate),		(peppermint,	
	1375 mg liquid maltitol,		spearmint, menthol,	
	490 mg sorbitol, 1.0 mg		and ethanol)	
	ethanol and 450 mg of		Liquid sorbitol (non-	
	propylene glycol		crystallising)	
			Sodium citrate	
	!		Disodium edetate	
	!		Sucralose	
	!		Sodium hydroxide	
			Purified water	
Soldesam 0.2 % Oral	Each 5 mL contains		Sodium benzoate	
drops (Laboratorio	10 mg dexamethasone		Propylene glycol	
Farmacologico	(as dexamethasone		Sodium dihydrogen	
Milanese, IT, SE)	sodium phosphate)		phosphate dihydrate	
	!		Sodium saccharin	
	!		Hydroxypropyl	
	!		betacyclodextrin	
			Sodium edetate	
	!		Sodium hydroxide	
			Purified water	
Extemporaneous	Each 5 mL contains 5 mg	Dissolve	Methyl	Storage: up to
preparation	dexamethasone (as	dexamethasone	parahydroxybenzoate	12 months in amber
5 mg/5 mL	dexamethasone	disodium phosphate	Banana essence	glass bottle below
(FNA monograph)	disodium phosphate)	and other solid	Disodium edetate	25 °C, not in fridge
	and 45.5 mg propylene	materials in purified	Sodium dihydrogen	or freezer
	glycol	water. Mix with the	phosphate dihydrate	
	!	sorbitol solution. Add	Disodium phosphate	
	!	methyl	dodecahydrate	
	!	parahydroxybenzoate	Propylene glycol	
		solution. Mix with	Sorbitol solution	
	1	banana essence.	crystallisable	
		Complete to volume	Purified water	
		with purified water.		
		See reference for		
		detailed instructions.		

16 October 2020 Page **3** of **6**



Product	Strength†	How to Formulate	Excipients‡	Comments
Oral solution (continued				
Extemporaneous preparation 5 mg/5 mL (Sociedad Española de Farmacia Hospitalaria)	Each 5 mL contains 5 mg dexamethasone (as dexamethasone sodium phosphate)	Dissolve 132 mg of dexamethasone sodium phosphate in 20 mL of preservative water. Dilute to 100 mL with simple syrup with preservative.	Preservative water* Simple syrup with preservative*	Storage: up to 2 months in amber glass bottle in fridge (2-8 °C)
Oral suspension				
Extemporaneous preparation 1 mg/mL (Santoveña-Estévez A, Dorta-Vera D, González-García I, et al. Pharm Technol Hosp Pharm 2018;3(2):59-70)	Each 5 mL contains 5 mg dexamethasone	Dexamethasone mixed with a citric/citrate buffer. Complete to volume with simple syrup. See reference for detailed instructions.	Simple syrup* Citric acid Sodium citrate	Storage: up to 15 days at 5 °C and 25 °C
Extemporaneous preparation 5 mg/mL (Binson G, Venisse N, Bacle A, et al. Pharm Technol Hosp Pharm 2017;2(4):193-201)	Each 5 mL contains 25 mg dexamethasone (as dexamethasone acetate)	Obtain a thick paste using 664.5 mg of dexamethasone acetate powder (corresponding to 600 mg of dexamethasone base) and 60 mL of OraPlus. Obtain a suspension by mixing, with constant stirring, with 60 mL OraSweet.	OraSweet* OraPlus*	Storage: up to 2 months in amber glass bottle; stable in fridge (2-8 °C) and at room temperature (20- 25 °C); no data on microbiological stability
Soluble tablet		0.40.1.001		
Glensoludex 2 mg, 4 mg and 8 mg Soluble tablets (Glenmark, UK)	Each tablet contains 2 mg / 4 mg/ 8 mg dexamethasone (as dexamethasone sodium phosphate) and 14.96 mg / 29.95 mg / 60.5 mg sodium		Sodium bicarbonate Disodium citrate 1.5hydrate Povidone K30 Sodium saccharin Sodium benzoate Yellow sunset	
Tablets (selection)				
Dexamethasone 0.5 mg Tablets (Centrafarm, NL)	Each tablet contains 0.5 mg dexamethasone and 103.4 mg lactose (as monohydrate)		Lactose monohydrate Maize starch Cellulose Povidone Sodium starch glycolate Magnesium stearate	
Dexamethasone 0.5 mg Tablets (Krka, BG, CZ, DE, HU, PL, RO, RS, SK, UK)	Each tablet contains 0.5 mg dexamethasone and 70 mg lactose (as monohydrate)		Lactose monohydrate Pregelatinised maize starch Colloidal anhydrous silica Magnesium stearate	

16 October 2020 Page **4** of **6**



Product	Strength†	How to Formulate	Excipients‡	Comments
Tablets (selection, conti	nued)			
Fortecortin 0.5 mg and 2 mg Tablets (Merck Serono, DE)	Each tablet contains 0.5 mg / 2 mg dexamethasone and 78.3 mg lactose (as monohydrate)		Colloidal anhydrous silica Magnesium stearate Sodium starch glycolate (type C) Sucrose Talc Maize starch Lactose monohydrate	
Dexamethasone 0.5 mg and 1.5 mg Tablets (Mibe, DE)	Each tablet contains 0.5 mg / 1.5 mg dexamethasone and 78.3 mg / 77.4 mg lactose (as monohydrate)		Lactose monohydrate Potato starch Talc Sodium starch glycolate (type A) Gelatin Magnesium stearate	
Dexamethasone 0.5 mg, 1.5 mg and 4 mg Tablets (Teva, NL)	Each tablet contains 0.5 mg / 1.5 mg / 4 mg dexamethasone and 95 mg / 157 mg / 250 mg lactose (as monohydrate)		Cellulose Sodium starch glycolate Magnesium stearate Lactose monohydrate Maize starch Pregelatinised starch	
Dexamethasone 1 mg and 4 mg Tablets (Abcur, DK, FI)	Each tablet contains 1 mg / 4 mg dexamethasone and 73 mg / 70 mg lactose (as monohydrate)		Lactose monohydrate Microcrystalline cellulose Croscarmellose sodium Magnesium stearate	
Dexamethasone 2 mg Tablets (Teva, NL, UK)	Each tablet contains 2 mg dexamethasone and 70 mg lactose (as monohydrate)		Lactose monohydrate Maize starch Magnesium stearate	
Dexamethasone 4 mg, 8 mg, 20 mg and 40 mg Tablets (Krka, BG, CZ, DE, DK, EE, ES, HR, HU, LT, LV, PL, PT, RO, RS, SI, SK, UK)	Each tablet contains 4 mg / 8 mg / 20 mg / 40 mg dexamethasone and 70 mg lactose (as monohydrate)		Lactose monohydrate Pregelatinised starch Colloidal anhydrous silica Magnesium stearate	
Neofordex 40 mg Tablets (Laboratoires CTRS, DK)	Each tablet contains 40 mg dexamethasone and 98.1 mg lactose (as monohydrate)		Lactose monohydrate Microcrystalline cellulose Magnesium stearate Colloidal anhydrous silica	

16 October 2020 Page **5** of **6**



Product	Strength†	How to Formulate	Excipients‡	Comments
Capsules				
Extemporanenous preparation 10-40 mg (FNA monograph)	Each capsule contains 10-40 mg dexamethasone		Primojel*	Cellulose is not used because of potential absorption of dexamethasone (Landín M, Martínez-Pacheco R, Gómez-Amoza JL, Int J Pharm 1993;91:143-9)

BCS=biopharmacetuical classification system

Preservative water: Methyl parahydroxybenzoate, propyl parahydroxybenzoate, purified water.

Simple syrup: sucrose (65%), purified water

Simple syrup with preservative: Sucrose, methyl parahydroxybenzoate, propyl parahydroxybenzoate, purified water.

Primojel: Calcium hydrogenphosphate dihydrate, carboxymethylamylum sodium, colloidal anhydrous silica.

16 October 2020 Page **6** of **6**

[†]Information obtained from section 2 of the SmPC for licensed products.

[‡]Excipients raising concern for children in bold. Information obtained from section 6.1 of the SmPC for licensed products.

^{*}OraSweet: Purified water, sucrose, glycerol, **sorbitol**, citrus-berry flavor, citric acid, sodium phosphate, methylparaben, potassium sorbate OraPlus: Purified water, microcrystalline cellulose, carmellose, xanthan gum, κ-**carrageenan**, calcium sulfate, trisodium phosphate, citric acid, sodium phosphate, **dimethicone**, methylparaben, potassium sorbate.