Dexamethasone
Newborn use only

2020

Alert	Dexamethasone is available as Dexamethasone phosphate or dexamethasone sodium phosphate. The conversion factor for dexamethasone: 1.2 mg dexamethasone phosphate = 1 mg dexamethasone 1.3 mg dexamethasone sodium phosphate = 1 mg dexamethasone There is a non TGA registered commercial product, Dexsol®oral syrup. However, a SAS form is required for supply.
Indication	To facilitate weaning from assisted ventilation and improve lung function in infants at risk of chronic lung disease. To facilitate extubation.
Action	Long acting glucocorticoid with potent anti-inflammatory action. No significant mineralocorticoid activity.
Drug type	Adrenal steroid hormone.
Trade name	IV: (1) DBL Dexamethasone sodium phosphate Pfizer, (2) DBL dexamethasone phosphate Hospira, (3) dexamethasone phosphate Alphapharm, (4) dexamethasone phosphate Mylan. Oral: Compounded by pharmacy in-house. Refer to special comments section. There is a non TGA registered commercial product, Dexsol®oral syrup. However, a SAS form is required for supply.
Presentation	IV preparations: All 4 IV preparations: 1 mL contains 4.4 mg of dexamethasone sodium phosphate equivalent to 4 mg dexamethasone phosphate and 3.4 mg of dexamethasone base. Oral: 0.05mg/mL, 0.1mg/mL, 0.5 mg/mL or 1 mg/mL solution or suspension – Prepared by pharmacy in-house. Refer to special comments section for further information.
Dose	**Low dose (DART) protocol** 0.075 mg/kg/dose 12 hourly for 3 days then, 0.05 mg/kg/dose 12 hourly for 3 days then, 0.025 mg/kg/dose 12 hourly for 2 days then, 0.01 mg/kg/dose 12 hourly for 2 days then cease. **High dose protocol – e.g., for term neonates with chronic lung disease** 0.25 mg/kg/dose 12 hourly for 3 days then, 0.15 mg/kg/dose 12 hourly for 3 days then, 0.1 mg/kg/dose 12 hourly for 3 days then, 0.05 mg/kg/dose 12 hourly for 3 days then, 0.025 mg/kg/dose 12 hourly for 6 days then cease. **Extubation protocol** 0.25 mg/kg 8 hourly for up to 3 doses. Commence 4 hours before extubation.
Dose adjustment Therapeutic hypothermia ECMO Renal impairment Hepatic impairment	 Not applicable Not applicable Not applicable Not applicable
Maximum dose	0.75 mg/kg/day
Total cumulative dose	Low dose (DART) protocol: 0.89 mg/kg High dose protocol: 3.6 mg/kg Extubation protocol: 0.75 mg/kg
Route	IV, oral.
Preparation	**IV:** Note: 4.4mg/mL of dexamethasone sodium phosphate = 4mg/mL of dexamethasone phosphate equivalent to 3.4mg/mL Dexamethasone.

	Draw up 0.6 mL (equivalent to 2 mg dexamethasone) and add 9.4 mL of sodium chloride 0.9% to make a final volume of 10 mL with a concentration of 0.2 mg/mL. If volume is too small, further dilute: Draw up 1 mL of solution (0.2mg of dexamethasone) and add 9 mL of sodium chloride 0.9% to make a final volume of 10mL with a concentration of 0.02 mg/mL. **Oral:** Prepared by pharmacy in-house (check which strength is stocked with Pharmacy Department). Strengths available: 0.05mg/mL oral solution or suspension 0.1mg/mL oral solution or suspension 0.5mg/mL oral solution or suspension (if volume is too small, further dilute: Draw up 1mL of solution or suspension (0.5mg dexamethasone) and add 9mL WFI to make a final volume of 10mL with a concentration of 0.05mg/mL). 1mg/mL oral solution or suspension (if volume is too small, further dilute: Draw up 1mL of solution or suspension (1mg dexamethasone) and add 9mL WFI to make a final volume of 10mL with a concentration of 0.1mg/mL). Dexamethasone 1mg = Dexamethasone phosphate 1.2mg = Dexamethasone sodium phosphate 1.3mg approx. Molecular mass (Dexamethasone phosphate) = 472.4 Molecular mass (Dexamethasone) = 392.5[12]
Administration	IV: Administer over 3−5 minutes. Oral: Administer with feeds to minimise gastric irritation. Oral Suspension: Shake the bottle well before drawing up required dose.
Monitoring	Blood glucose levels (BGLs) at least daily. When on oral feeds measure BGL only if there is glucose in urine. Blood pressure at least daily. Electrolytes.
Contraindications	Untreated systemic infections.
Precautions	Use preservative free drug where possible. Avoid early (<8 days) treatment, higher dose and longer courses where possible to reduce side effects. Avoid concurrent use with NSAIDs for PDA treatment. Corticosteroids may increase susceptibility to or mask the symptoms of infection.
Drug interactions	Barbiturates, phenytoin and rifampicin may increase the metabolism of dexamethasone. Antithyroid agents may decrease the metabolism of dexamethasone.
Adverse reactions	Early (< 8 days) postnatal corticosteroids cause short-term adverse effects including gastrointestinal bleeding, intestinal perforation, hyperglycaemia, hypertension, hypertrophic cardiomyopathy and growth failure. Late (after seven days) postnatal corticosteroids in high doses in particular are associated with short-term side effects including gastrointestinal bleeding, higher blood pressure, glucose intolerance, severe retinopathy of prematurity and hypertrophic cardiomyopathy. Other effects include: Hypertriglyceridemia in association with hyperinsulinism and raised free fatty acids. Increase in total and immature neutrophil counts; increase in platelet count. Adrenal insufficiency is associated with higher doses (initial >0.2 mg/kg/day) longer courses (>14 days) of dexamethasone. Myocardial hypertrophy and outflow obstruction may occur with higher doses and prolonged courses of dexamethasone. May increase risk of infection.
Compatibility	Fluids: Glucose 5%, sodium chloride 0.9% Y-site : Amino acid solutions, aciclovir, amifostine, amikacin, anidulafungin, aztreonam, bivalirudin, cisatracurium, dexmedetomidine, fentanyl, filgrastim, fluconazole, foscarnet, granisetron, heparin

<table>
<tr><td></td><td>sodium, hydrocortisone sodium succinate, hydromorphone, linezolid, methadone, morphine sulfate, pethidine, piperacillin-tazobactam, potassium chloride, remifentanil, zidovudine.</td></tr>
<tr><td>Incompatibility</td><td>Fluids: No information.

Y-site: Calcium chloride, calcium gluconate, caspofungin, chlorpromazine, ciprofloxacin, dobutamine, erythromycin, esmolol, gentamicin, glycopyrrolate, haloperidol lactate, labetalol, levomepromazine, magnesium sulfate, midazolam, mycophenolate mofetil, pentamidine, phentolamine, promethazine, protamine, rocuronium, tobramycin.</td></tr>
<tr><td>Stability</td><td>IV: Diluted solution is stable for 24 hours at 2−8°C
Oral: As per Pharmacy Department.</td></tr>
<tr><td>Storage</td><td>Ampoule: Store below 25°C. Protect from light.
Oral: As per Pharmacy Department – Some formulations are stored at room temperature (below 25°C) while others are stored refrigerated (2−8°C). Protect from light.</td></tr>
<tr><td>Excipients</td><td>IV injections are brand specific, please refer to manufacturer’s information.
DBL Pfizer: Sodium citrate dihydrate, Creatinine, Hydrochloric acid, Sodium hydroxide
Mylan: Sodium citrate, creatinine and water for injections
DBL Hospira: Sodium citrate dihydrate; disodium edetate; hydrochloric acid; sodium hydroxide; sodium sulfite.
Alphapharm: Sodium citrate anhydrous and creatinine

Oral preparations: Many preparations exist, please consult pharmacy. An example is shown below in special comments.</td></tr>
<tr><td>Special comments</td><td><u>IV dexamethasone preparation as a straight oral administration</u>
A small study in healthy adults showed an absolute bioavailability of around 76% when dexamethasone sodium phosphate injection was administrated orally undiluted and authors recommended a dose adjustment [13]. No studies have been reported in neonates.

<u>Extemporaneous preparation</u>

Example of an oral dexamethasone 0.5mg/mL extemporaneous preparation:[14]

<table>
<tr><th>Ingredients</th><th>Brand</th><th>Form</th><th>Quantity</th></tr>
<tr><td>Dexamethasone phosphate injection 4mg/mL</td><td>Mylan</td><td>Ampoule</td><td>3mL</td></tr>
<tr><td>OraBlend</td><td>Perrigo</td><td>Liquid</td><td>To 20mL</td></tr>
</table>

Dexamethasone 1mg = dexamethasone phosphate 1.2mg

Method:

Withdraw 3mL of dexamethasone injection into a syringe using a filter needle.
Transfer the contents of the syringe into a graduated measure.
Make up to final volume with OraBlend and mix well.
Transfer the final mixture into a plastic amber bottle[15] and secure lid tightly. Label appropriately.
Shake the mixture before use.

Storage: Refrigerate (2−8°C), do not freeze. Protect from light.[14,15]

Expiry: 28 days after preparation.[14]</td></tr>
<tr><td>Evidence</td><td>Refer to full version.</td></tr>
<tr><td>Practice points</td><td>Refer to full version.</td></tr>
</table>

References	Refer to full version.

VERSION/NUMBER	DATE
Original	4/11/2015
Revised **2.0** **3.0**	 24/04/2017 31/10/2019
Current 4.0	30/01/2020
REVIEW	30/01/2025

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