Dexamethasone
Newborn use only

2021

Alert	Dexamethasone is available as Dexamethasone phosphate, dexamethasone sodium phosphate or dexamethasone base. Dexamethasone 1mg = Dexamethasone phosphate 1.2mg = Dexamethasone sodium phosphate 1.3mg approximately. In this formulary, differentiation is not made in the prescription or preparation of dexamethasone salts versus dexamethasone base as the dosage difference among them is not clinically significant and detailed prescription of salt and base is prone to errors. 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: DBL Dexamethasone sodium phosphate Pfizer, DBL dexamethasone phosphate Hospira, dexamethasone phosphate Alphapharm, 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	**NOTE: Daily dose can be given as single daily dose instead of 12 hourly doses.** **Low dose (DART) regimen (total cumulative dose 0.89 mg/kg)(1, 2)** 75 microgram/kg/dose 12 hourly for 3 days then, 50 microgram/kg/dose 12 hourly for 3 days then, 25 microgram/kg/dose 12 hourly for 2 days then, 10 microgram/kg/dose 12 hourly for 2 days then cease. **Moderate dose protocol (total cumulative dose 3.6 mg/kg) (modified 18-day regimen)(3)** 250 microgram/kg/dose 12 hourly for 3 days then, 150 microgram/kg/dose 12 hourly for 3 days then, 100 microgram/kg/dose 12 hourly for 3 days then, 50 microgram/kg/dose 12 hourly for 3 days then, 25 microgram/kg/dose 12 hourly for 6 days then cease. **High dose regimen (total cumulative dose 7.98 mg/kg) (modified 42-day regimen)(3-5)** 250 microgram/kg/dose BD x 3days then, 150 microgram/kg/dose BD x 3 days then, 135 microgram/kg/dose BD x 3days then, 120 microgram/kg/dose BD x 3days then, 110 microgram/kg/dose BD x 3days then, 100 microgram/kg/dose BD x 3days then, 90 microgram/kg/dose BD x 3days then, 80 microgram/kg/dose BD x 3days then, 70 microgram/kg/dose BD x 3days then, 65 microgram/kg/dose BD x 3days then, 60 microgram/kg/dose BD x 3days then, 50 microgram/kg/dose BD x 3days then, 100 microgram/kg/dose DAILY on alternate days x 3 doses

	Extubation regimen(6) 0.25 mg/kg 8 hourly for up to 3 doses. Commence 4 hours before extubation.
Dose adjustment	Therapeutic hypothermia – Not applicable. ECMO – Not applicable. Renal impairment – Not applicable. Hepatic impairment – Not applicable.
Maximum dose	0.75 mg/kg/day
Total cumulative dose	Low = less than 2 mg/kg; Moderate = 2 to 4 mg/kg; and High = greater than 4 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).
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 (19,20): Glucose 5%, sodium chloride 0.9% Y-site (19,20) : Acetaminophen, aciclovir, amikacin, aminophylline, amphotericin B cholesteryl sulfate complex, amphotericin B lipid complex, ascorbic acid injection, atenolol, atracurium, atropine, azithromycin, aztreonam, cefazolin, cefepime, cefotaxime, cefoxitin, ceftazidime, ceftriaxone, chloramphenicol, clindamycin, cloxacillin, dexmedetomidine, digoxin, diltiazem, dopamine, anlaprilat, ephedrine, epinephrine, epoietin alfa, fentanyl, fluconazole, furosemide, ganciclovir, glycopyrrolate, heparin, hydrocortisone sodium succinate, imipenem-cilastatin, indomethacin sodium trihydrate, insulin regular, isoproterenol, lidocaine, lincomycin, linezolid, lorazepam, Meropenem, methylprednisolone sodium succinate, metoprolol, metronidazole, milrinone, morphine sulfate, naloxone, nitroglycerin, nitroprusside sodium, norepinephrine, octreotide, oxacillin, pamidronate, pancuronium, penicillin G, pentobarbital, phenobarbital, piperacillin, piperacillin-tazobactam, potassium acetate, potassium chloride, procainamide, propofol, propranolol, pyridoxine, ranitidine, remifentanil, sodium acetate, sodium bicarbonate, streptokinase, succinylcholine, theophylline, thiamine, thiopental, ticarcillin, ticarcillin-clavulanate, tolazoline, urokinase, vancomycin, vasopressin, vecuronium, verapamil, zidovudine. **Variable compatibility** (19)**:** Ampicillin, azathioprine, erythromycin lactobionate, hydralazine.
Incompatibility	Fluids (19): **Not tested:** glucose 10%, glucose 5% in sodium chloride 0.9%, glucose 5% in sodium chloride 0.45%, sodium chloride 0.45% Y-site (19,20): Amiodarone, calcium chloride, calcium gluconate, caspofungin, chlorpromazine, ciprofloxacin, dobutamine, erythromycin, esmolol, gentamicin, glycopyrrolate, haloperidol lactate, labetalol, magnesium sulfate, midazolam, pentamidine, phentolamine, promethazine, protamine, rocuronium, tobramycin.
Stability	IV: Diluted solution is stable for 24 hours at 2−8°C Oral: As per Pharmacy Department.
Storage	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.
Excipients	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.
Special comments	<u>IV dexamethasone preparation as a straight oral administration (7)</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.(15) No studies have been reported in neonates. <u>Extemporaneous preparation</u> Example of an oral dexamethasone 0.5mg/mL extemporaneous preparation:

Ingredients	Brand	Form	Quantity

	Dexamethasone phosphate injection 4mg/mL	Mylan	Ampoule	3mL
	OraBlend	Perrigo	Liquid	To 20mL

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.(8, 9)
Expiry: 28 days after preparation.(8)

Evidence

Efficacy:

Late (>7 days) postnatal corticosteroids for chronic lung disease in preterm infants: Systematic review of 21 RCTs (1424 participants) found late steroid treatment was associated with a reduction in neonatal mortality (at 28 days) but no reduction in mortality at 36 weeks, at discharge, or at latest reported age. Benefits of delayed steroid treatment included reductions in failure to extubate; chronic lung disease at 28 days and at 36 weeks' postmenstrual age; need for late rescue treatment with dexamethasone; discharge on home oxygen; and death or chronic lung disease both at 28 days of life and at 36 weeks' postmenstrual age.
There was no significant difference in infection, gastrointestinal bleeding or necrotising enterocolitis. Adverse effects included hyperglycaemia, glycosuria, and hypertension, an increase in severe retinopathy of prematurity but no significant increase in blindness. The combined rate of death or cerebral palsy, major neurosensory disability, and the combined rate of death or major neurosensory disability were not significantly different. There were no differences in later childhood outcomes for respiratory health or function, blood pressure, or growth, and fewer participants had a clinically important reduction in forced expired volume in one second on respiratory function testing in the dexamethasone group. (1) (LOE I, GOR B)

A meta-regression of randomised trials of postnatal corticosteroids in preterm infants found a relationship between risk of chronic lung disease and risk of death or CP. With risks for CLD below 35%, corticosteroid treatment significantly increased the chance of death or CP, whereas with risks for CLD exceeding 65%, it reduced this chance. There was no difference overall in risk of death or cerebral palsy. The analysis suggests postnatal corticosteroids should be restricted to ventilated infants predicted to have ≥ 50% risk of chronic lung disease. (10, 11) (LOE III, GOR C)
Conclusion: The benefits of late corticosteroid therapy may not outweigh actual or potential adverse effects.(1) It is recommended to reserve the use of late corticosteroids for infants who cannot be weaned from mechanical ventilation and are at ≥ 50% risk of chronic lung disease.

Early (< 8 days) postnatal corticosteroids for preventing chronic lung disease in preterm infants: Early corticosteroid treatment facilitates extubation and reduces the risk of chronic lung disease, patent ductus arteriosus and severe retinopathy of prematurity. However, it causes short-term adverse effects including gastrointestinal bleeding, intestinal perforation, hyperglycaemia, hypertension, hypertrophic cardiomyopathy and growth failure. Long-term follow-up studies report an increased risk of abnormal neurological examination and cerebral palsy. There was no difference in infection. The benefits of early postnatal corticosteroid treatment, particularly dexamethasone, may not outweigh the adverse effects of this treatment.(12) (LOE I, GOR B)

Systemic corticosteroid regimens for preventing chronic lung disease in preterm infants:
A systematic review of systemic corticosteroid regimens included 14 studies.(13) Eight compared total cumulative doses of dexamethasone: Low = less than 2 mg/kg; moderate = 2 to 4 mg/kg; and high = greater than 4 mg/kg.

Moderate dexamethasone dose versus a low-dosage regimen: There was no difference in death and BPD (RR 0.83, 95% CI 0.50 to 1.40; 154 infants, 4 RCTs), or death or cerebral palsy (RR 0.78, 95% CI 0.28 to 2.18; 109 infants, 2 RCTs).
Moderate dexamethasone dose versus a high-dosage regimen: meta-analysis found an increased risk of BPD at 36 weeks PMA (RR 1.50, 95% CI 1.01 to 2.22; RD 0.26, 95% CI 0.03 to 0.49; NNTH 4, 95% CI 1.9 to 23.3; I2 = 0%, 2 studies, 55 infants), and increased risk of abnormal neurodevelopmental outcome (RR 8.33, 95% CI 1.63 to 42.48; RD 0.30, 95% CI 0.14 to 0.46; NNTH 4, 95% CI 2.2 to 7.3; I2 = 68%, 2 studies, 74 infants) when using a moderate cumulative-dosage regimen. Composite outcomes of death or BPD (RR 1.35, 95%CI 1.00 to 1.82; 55 infant, 2 RCTs) and death or abnormal neurodevelopmental outcome (RR 3.37, 95% CI 1.42 to 7.99; 81 infants, 2 RCTs) were increased in the moderate compared to the higher dose regimen. Four studies (762 infants) of early initiation of dexamethasone therapy versus a moderately early or delayed initiation found no significant differences in the primary outcomes. Two RCTs (197 infants) of continuous versus a pulse dexamethasone regimen found an increased risk of the combined outcome death or BPD when using the pulse therapy. Two RCTs (109 infants) investigating a standard regimen versus a participant-individualized course of dexamethasone showed no difference in the primary outcome and long-term neurodevelopmental outcomes.

The low dose dexamethasone protocol (DART trial) facilitated extubation and shortened duration of intubation in ventilator-dependent, very preterm/extremely low birth weight infants, without obvious short-term complications. [Twice-daily doses of a 10-day tapering course of dexamethasone sodium phosphate (0.15 mg/kg per day for 3 days, 0.10 mg/kg per day for 3 days, 0.05 mg/kg per day for 2 days, and 0.02 mg/kg per day for 2 days; total cumulative dose = 0.89 mg/kg)].(14)

High dose trials: RCT by Cummings at al included 36 ventilator dependent preterm infants of GA < 30 weeks. They randomly received dexamethasone for 42 days (n=13) or 18 days (n=12) or placebo (n=110). Infants in the 42-day dexamethasone group were weaned from the mechanical ventilator faster than the 18-day group and the placebo group. Hyperglycemia, occult gastric bleed, suspected or proven sepsis and retinopathy of prematurity rates in the 42-day groups were not different from the control group. Need for red cell transfusion was lower in the 42 days group. Similarly, normal neurological examination and Bayley developmental indices >84 at 15 months of age were higher in the 42-day group (78%) compared to the 18 day group (22%) and the placebo group (40%).(3) Papile et al randomised 371 ventilator dependent very low birth weight infants to receive a 2 week course of dexamethasone (cumulative dose: 3.25 mg/kg) at either 14 days or 28 days. There was no difference in the risk of death before discharge or development of chronic lung disease between the two regimens. But nosocomial infections and hyperglycemia were higher in infants who received dexamethasone at 14 days while the mean arterial blood pressure was higher in infants who received dexamethasone at 28 days.(5) Marr et al J randomised 59 infants of postnatal age of 10-21 days born at <27 weeks of gestation and evolving chronic lung disease (Ventilator support, mean airway pressure > 8 cm H_2O and FiO_2 > 60%) were randomised to receive either 42-day (n= 30) or 9-day dexamethasone course (n=29). Nineteen of 29 infants (66%) in the 9-day group received only 1 course of dexamethasone. During the study period, infants in the 42-day group received a total dexamethasone dose of 7.98 mg/kg. Infants in the 9-day group received a total dexamethasone dose of 2.63, 5.25, or 7.88 mg/kg depending upon the number of 9-day courses (1, 2, or 3) received. Infants in the 42-day group had shorter duration of ventilation (25 vs 37 days) and received fewer blood transfusions (2 vs 3.5) Intact survival at school age was significantly increased in the 42-day group (75%) compared with the 9-day group (34%).(4)

Intravenous dexamethasone for extubation of newborn infants: Dexamethasone reduces the need for endotracheal reintubation of neonates after a period of intermittent positive pressure ventilation. In view of the lack of effect in low risk infants and the documented and potential side effects, restrict use to infants at increased risk for airway oedema and obstruction, such as those who have received repeated or prolonged intubations. Dose regimens used 0.25-0.5 mg/kg from 1-3 doses.(6) [LOE I, GOR C]

	Side effects: Late (≥7 days) postnatal corticosteroid use was associated with no significant difference in infection, gastrointestinal bleeding or necrotising enterocolitis, but adverse effects included hyperglycaemia, glycosuria, and hypertension, an increase in severe retinopathy of prematurity but no significant increase in blindness.(1) [LOE I] Early (<7 days) postnatal corticosteroid use was associated with gastrointestinal bleeding, intestinal perforation, hyperglycaemia, hypertension, hypertrophic cardiomyopathy and growth failure. Long-term follow-up studies report an increased risk of abnormal neurological examination and cerebral palsy.(12) [LOE I] Adrenal suppression and myocardial hypertrophy: Higher doses (starting >0.2mg/kg) and prolonged courses (>14 days) may be associated with myocardial hypertrophy and adrenal suppression.(15, 16) (LOE II, GOR B) Infection: Systematic reviews of trials of early and late postnatal corticosteroids found no difference in infection rate overall.(1, 12, 13) However, a crossover trial of dexamethasone-placebo versus placebo-dexamethasone reported increased nosocomial infection in the initial time period in the dexamethasone group.(5) Neutrophils: Dexamethasone increased total and immature neutrophils and platelet count peaking on day 7.(17) Hypertriglyceridaemia: Dexamethasone induces hypertriglyceridemia in association with hyperinsulinism and raised free fatty acids.(18)
Practice points	Recommendations on the optimal type of corticosteroid, the optimal dosage, or the optimal timing of initiation for the prevention of BPD in preterm infants cannot be made based on current level of evidence.(13) The benefits of early (before 7 days) corticosteroids may not outweigh the harms so cannot be recommended.(12, 13) [LOE I, GOR C] It is recommended to reserve the use of late (≥7 days) corticosteroids for infants who cannot be weaned from mechanical ventilation and are at ≥ 50% risk of chronic lung disease.(1, 10, 11, 13) [LOE I, GOR C]. There is insufficient evidence to recommend a participant-individualized course of dexamethasone for infants.(13) Parents should be informed of the potential benefits and harms of postnatal corticosteroid treatment.
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