Prednisolone Newborn Use Only

Alert	Routine use of prednisolone for prevention of chronic lung disease is not recommended.		
Indication	Treatment of severe bronchopulmonary dysplasia ≥36 weeks gestation		
Action	Predominantly glucocorticoid effects with minimal mineralocorticoid effects		
	 Decreases inflammation by suppression of migration of polymorphonuclear leukocytes ar 		
	reversal of increased capillary permeability.		
	 suppresses the immune system by reducing activity and volume of the lymphatic system 		
Drug Type	Synthetic glucocorticoid.		
Trade Name	Redipred		
	Predmix (not first choice due to propylene glycol content)		
Presentation	Liquid: 5mg/mL (recommended)		
	Note: Prednisolone tablets may be used if there is stock availability issues of the liquid products. Contact		
	local pharmacy department for appropriate preparation using tablets.		
Dose	NOTE: It is highly recommended to consult paediatric respiratory specialist before commencing		
	prednisolone therapy.		
	14-day ORAL regimen course ¹		
	Day 1 to Day 5 (5 days): 1 mg/kg/dose 12 hourly,		
	Day 6 to Day 8 (3 days): 1 mg/kg/dose 24 hourly,		
	Day 10 – Day 14 (6 days): 1 mg/kg/dose 48 hourly		
Dose adjustment	Therapeutic hypothermia – Not applicable.		
	ECMO- Not applicable.		
	Hepatic impairment – Metabolised in liver, but no specific dose adjustment is suggested.		
	Renal impairment – No dose adjustment.		
Route	Oral/OGT/NGT		
Preparation	N/A		
Administration	Administer undiluted with feeds		
Monitoring	Blood pressure, weight, BGL, electrolytes, bone mineral density, haemoglobin, signs of infection		
Contraindications	Uncontrolled infections		
	Systemic fungal infections		
	Known hypersensitivity to prednisolone or prednisone		
Precautions	Adrenal suppression		
	Immunosuppression		
	Metabolic bone disease		
Drug Interactions	Phenobarbital increases prednisolone's metabolism and may reduce its activity		
Adverse Reactions	Vomiting, abdominal distension, diarrhoea		
	Increased appetite		
	Agitation		
	Hyperglycaemia		
· ·	Hypokalaemia		
	Hypertension		
	Reduced growth (long term treatment)		
	 Osteopenia (long term treatment) Reduced wound healing 		
	Sodium and water retention		
Overdose	For further information, contact the Poisons Information Centre on 131 126 (Australia).		
Compatibility	Not applicable.		
Incompatibility			
	Not applicable.		
Stability	Discard commercial liquids 4 weeks after opening		
Storage	Redipred brand store at room temperature below 25°C		
	Predmix brand store refrigerated at 2–8°C		

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Excipients	Redipred: Sorbitol solution (70%) non-crystallising, disodium edetate, monobasic sodium phosphate,
Excipients	dibasic sodium phosphate, methyl hydroxybenzoate, propyl hydroxybenzoate, nature identical raspberry
	flavour 08-3326 and water purified.
	Predmix: Propylene glycol, methyl hydroxybenzoate, propyl hydroxybenzoate, dibasic sodium phosphate
	dodecahydrate, monobasic sodium phosphate, disodium edetate and water purified.
Special Comments	Immunise one month before starting or at least one month after ceasing corticosteroids.
Evidence	Background
	Bronchopulmonary dysplasia (BPD) in preterm infants is associated with delayed brain maturation and
	diffuse white matter anomalies that are associated with increased risk of neurodevelopmental
	impairment. ² Dexamethasone has been acknowledged in multiple trials as a long-acting glucocorticoid
	that can be used to prevent or treat developing BPD. Methylprednisolone and prednisolone are alternate
	steroids, and there is emerging evidence to support their use in some infants at high risk of BPD or
	established BPD. Both prednisolone and methylprednisolone have been safely used for other pulmonary
	diseases, primarily within the paediatric asthma population, but there is a paucity of available evidence
	for their use in the neonatal population.
	Efficacy
	There are no published studies on commencement of dexamethasone for treatment of BPD in preterm
	infants beyond 36 weeks gestation. There are 3 retrospective studies reporting on the efficacy of
	prednisolone/methylprednisolone for severe BPD in preterm neonates beyond 36 weeks corrected
	gestation.
	A single centre retrospective cohort study by Bhandari et al, assessed 385 infants of whom 131 (34%)
	received oral prednisolone to support weaning from oxygen at 36 weeks postmenstrual age. ¹ 63% of
	these infants were deemed responsive to oral prednisolone therapy and able to be weaned from oxygen,
	with lower pulmonary acuity scores than those infants non-responsive to treatment. Predictive
	responsiveness to oral prednisolone therapy identified a capillary PCO2 value of < 48.5 mmHg had a
	sensitivity of 50% and specificity of 89.7%, with positive and negative predictive values of 89.1% and
	51.8%, respectively. The dose of oral prednisolone used in Bhandari regimen was 2 mg/kg/day in 2
	divided doses for 5 days, then 1 mg/kg/day daily for 3 days, and then 1 mg/kg/dose every other day for 3
	doses. It was noted however that many of this group may also have received treatment with
	dexamethasone prior to commencement of prednisolone.
	A single-centre retrospective cohort study by Linafelter et al, identified 43 infants with a mean
	gestational age of 26 weeks, who were treated with an extended course (≥ 30 days) of prednisolone for
	severe BPD, using pulmonary severity score (PSS) as a primary outcome measure. The average age at
	start of prednisolone treatment was 42.5 ± 5.9 weeks; while the median duration and median cumulative
	dose of prednisolone therapy were 67 (IQR 57–107) days and 61.3 (IQR 39.9–93.3) mg/kg, respectively. ³
	PSS decreased after 1 week of prednisolone therapy (mean difference, 0.19; 95% Cl, 0.01 to 0.37;
	ρ = 0.03). No further reduction in PSS was noted despite continued treatment. Length z-scores decreased
	after 4 weeks of continued treatment (mean difference 0.6; 95% CI 0.01 to 1.1; P = 0.04), while weight
	and head circumference did not change. ³
	Another retrospective study by Liviskie et al, described the use of prednisolone for late treatment of
	pulmonary disease in infants with established BPD, after the first month of life. This study identified 34
	patients where prednisolone treatment was initiated at a mean postmenstrual age of 41.7 weeks.
	Typically, 1-2 mg/kg/d and weaned by 0.5 every 5-7 days (>30 day course). A significant decrease in PSS
	was observed (p<0.001) without rebound following discontinuation of treatment. ⁴ This study, conversely,
	did not identify any significant impact on anthropometric measures.
	Safety of dexamethasone versus prednisolone or methylprednisolone
	A secondary analysis of a multi-centre randomised controlled trial (Preterm Erythropoietin
	Neuroprotection – PENUT trial) reported 2-year neurodevelopmental outcomes in extremely preterm
	infants treated with dexamethasone, methylprednisolone, and prednisolone. The study identified an
	association between reduced BSID III scores and > 14 days treatment with dexamethasone. The median
	(IQR) start day was 29 (20-44) days for dexamethasone and 53 (30-90) days for prednisolone or
	methylprednisolone. The median (IQR) total days of exposure was 10 (5-15) days for dexamethasone and
	13 (6-25) days for prednisolone or methylprednisolone. The median (IQR) cumulative dose of

dexamethasone was 1.3 (0.9-2.8) mg/kg. After adjusting for potential confounders, treatment with dexamethasone for longer than 14 days was associated with worse neurodevelopmental outcomes. The same finding was not identified in the methylprednisolone and prednisolone group however the numbers in this cohort were small (n=99) and brains were more mature at the time of exposure. ⁵ This subgroup analysis of the PENUT frial demonstrated no long term neurologic complications from prednisolone: se starting on average at day 50 of life and continued for an average of 13 days. There were also some benefits on neurodevelopment for the infants treated with 8 to 14 days of prednisolone. ³ ANMF consensus: secondary analysis of PENUT frial reported worse neurodevelopmental outcomes with long courses of dexamethasone and no such effect was seen with short courses of either prednisolone or methylprednisolone. However, subgroup analyses of RCI s carry limitations such aspoor definitions, low statistical power, and inflated type lerror due to multiple hypothese stating. Similarly, a long course (>30 days) of prednisolone was shown to decrease length z-scores. ³ A short Courses of oral prednisolone may be considered in weaning off respiratory support in preterm inflated spee ropotheyulinonary dysplasia. It is highly recommended to consult paediatric respiratory specialist before commending prednisolone therapy. Pharmacokinetics Prednisolone is readily absorbed from the gastrointestinal tract. It is mostly metabolised in liver and excreted in urine. Safety No specific adverse events have been reported with short courses of prednisolone in the above- mentioned studies. However, extended course of prednisolone/s as associated with reduced length z scores. ³ Vaccines post prednisolone: Australian Immunisation handbook has made the following recormendations for i		deversether	0.0.2.0) ma/li= After !!	which for a should be affected and the start with		
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