University Hospitals of NICU: IV Dexamethasone Derby and Burton NHS Foundation Trust

Presentation:	Injection (Hospira brand): 1ml vials of 3.3 mg/mL dexamethasone base ≡ 4.3 mg/mL dexamethasone sodium phosphate
	Alert: different brands of injection or oral solution contain different amounts or salts of
	dexamethasone therefore they are not necessarily interchangeable. Dexamethasone is available
	as base, phosphate or sodium phosphate. Conversion factors:
	• 1.2 mg dexamethasone phosphate = 1 mg dexamethasone base
	• 1.3 mg dexamethasone sodium phosphate = 1 mg dexamethasone base
Indication:	Treatment of very severe established chronic lung disease (CLD) in neonates
	Treatment of post-intubation laryngeal oedema
Dose:	1) <u>Treatment of severe CLD (See separate Management of Chronic Lung Disease of</u>
	Prematurity - Paediatric Full Clinical Guideline NIC RC 14):
	Use minimum effective dose and shortest possible duration.
	Lower dose regimen (DART trial schedule) – preferred regimen:
	<u>Doses are given as dexamethasone sodium phosphate</u>
	150 micrograms/kg daily in 2 divided doses for 3 days,
	100 micrograms/kg daily in 2 divided doses for 3 days,
	50 micrograms/kg daily in 2 divided doses for 2 days
	20 micrograms/kg daily in 2 divided doses for 2 days
	If no response, consider repeating above course or use the higher dose regime:
	Higher dose regime
	Doses are given as dexamethasone sodium phosphate
	500 micrograms/kg daily in 2 divided doses for 3 days
	300 micrograms/kg daily in 2 divided doses for 3 days
	200 micrograms/kg daily in 2 divided doses for 2 days
	100 micrograms/kg daily in 2 divided doses for 2 days
	50 micrograms/kg once daily for 4 days
	Consider shortening course if there is a good early response
	Consider a longer course if patient deteriorates as the dose is being weaned down.
	2) Treatment of post-intubation laryngeal oedema (dexamethasone sodium phosphate):
	250micrograms/kg every 8 hours for 3 doses, started at least 4 hours prior to extubation
Route of	See below for example calculations
administration:	Slow IV injection over 3-5 minutes.
	Give undiluted or dilute in sodium chloride 0.9% or glucose 5% to a volume appropriate for
	patient's fluid intake.
	Rapid IV injection of large doses may cause cardiovascular collapse, so administer slowly.
Instructions for	
preparation:	IV example:
	Baby, 1.5kg needs dexamethasone sodium phosphate 150 micrograms/kg daily in 2 divided
	doses for 3 days:
	 Prescribe <u>150 x 1.5</u> = 112.5 microgram twice daily for 3 days
	 Product (Hospira injection brand) is 1ml vials of 4.3mg/mL (4300 microgram/mL) dexamethasone sodium phosphate

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	 Draw up 1ml and dilute to a total 10ml with sodium chloride 0.9% or glucose 5% to give a solution of 4300 microgram in 10ml Measure 112.5 x 10 = 0.26ml in a 1ml syringe and give slowly 4300
Prescribing	RDH – prescribe on paper NICU chart QHB – prescribe on Meditech
Known compatibility issues	See Medusa for compatibility information.
Additional Comments:	Please note that when using the oral liquid for the DART regimen babies will be given up to 10 times the EMA recommended daily limit of propylene glycol of 1mg/kg/day. If the high dose regimen is used this will be even higher. Propylene glycol accumulation is widely reported to potentially result in hyperosmolarity, lactic acidosis or hepato-renal toxicity though a Belgian study concluded that a median exposure of 34 mg/kg/day propylene glycol was associated with renal, metabolic and hepatic tolerance in neonates. Exposure of neonates to potentially toxic excipients is widely documented in the literature and no safe alternative to this has yet been identified for dexamethasone. GI cover with omeprazole should be considered for all patients.

Reference No: MONO-PAEDS/548/23

Note: The contents of this monograph should be read in conjunction with information available in the BNFC and Medusa

References:

Doyle LW, Davis PG, Morley C et al. Low dose dexamethasone facilitated extubation among chronically ventilator dependent infants: A Multicentre, International, Randomised, Controlled trial. Pediatrics 2006; 117:75-83

Medusa Injectable medicines guide, accessed via https://medusa.wales.nhs.uk/IVGuideDisplay.asp on 22/12/23

Leeds Teaching Hospitals NHS Trust Neonatal Unit Administration Guide Dexamethasone, accessed via http://www.leedsformulary.nhs.uk/docs/NNU%20Dexamethasone%20monograph.pdf?UNLID=1019378343201972416151 on 7.5.20

Australasian Neonatal Medicines Formulary (ANMF) Dexamethasone. The State of New South Wales (NSW Health) 2019

https://www.seslhd.health.nsw.gov.au/sites/default/files/groups/Royal Hospital for Women/Neonatal/Neomed/neo20dexamethasonefull.pdf on 20/12/23

<u>SOUTH GLASGOW UNIVERSITY HOSPITALS NHS TRUST (perinatalnetwork.scot)</u> accessed 22/12/23 Valeur et al. Excipients in Neonatal Medicinal Products: Never Prescribed, Commonly Administered. Pharmaceutical Medicine 2018:32:251-8

Wiley Blackwell. Neonatal Formulary, Drug Use in Pregnancy and the First Year of Life 8th Edition 2015. BMJ books.

Summary of product characteristics Dexamethasone 2mg/5ml Thame <u>Dexamethasone 2mg/5ml Oral Solution - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)</u> accessed 22/12/23

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Document control sheet

GUIDELINE NUMBER	MONO-PAEDS/548/23
AREA IN WHICH THIS MONOGRAPH APPLIES	NICU

DIVISIONAL AUTHORISATION			
GROUP	DATE		
Paediatric monograph review group	29/12/23 (Bhemigo- Consultant)		

AUTHORS		
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If review:

	Position	Date
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Checked by:	Lamia Ahmed Advanced Clinical Pharmacist- Women's and Children's	December 2023

Change history:

Changes Reference	Change details	Date
1	Higher dose regimen added to mirror separate Management of Chronic Lung Disease of Prematurity - Paediatric Full Clinical Guideline. Clarification of doses in terms of dexamethasone salt and calculation examples added. Review of products used vs excipients.	July 2020
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2	Addition of prescribing for QHB prescribing. Replacement of compatibility reference to 'see Medusa'. Removal of ranitidine as there is a long-term supply issue.	December 2023
	Removal of Oral example and oral instructions	December 2023
3		