University Hospitals of Derby and Burton NHS Foundation Trust

NICU: Phenytoin

Reference No: MONO-PAEDS/521

<table>
<tr><td>Presentation:</td><td>Phenytoin sodium 250 mg in 5 ml injection</td></tr>
<tr><td>Indication:</td><td>• Status epilepticus
• Prolonged convulsive epileptic seizure
• Management of neonatal seizures</td></tr>
<tr><td>Dose:</td><td>Loading dose by IV infusion using SMART PUMP:
Neonate:

<table>
<tr><th>Dose</th><th>Indication</th><th>Maximum rate of administration required for SMART pump</th><th rowspan="3">This ensures that the loading dose is given over at least 20 minutes</th></tr>
<tr><td>18mg/kg</td><td>Seizures</td><td>0.9mg/kg/minute</td></tr>
<tr><td>20mg/kg</td><td>Status</td><td>1 mg/kg/minute</td></tr>
</table>

Maintenance dose by slow IV injection or infusion using SMART pump adjusted according to response and serum levels (see below):

Neonate: 2.5-5 mg/kg twice daily, at a rate of no more than 1 mg/kg/minute</td></tr>
<tr><td>Route of administration:</td><td>Administer into a central venous access device or large vein as phenytoin is highly irritant. Rapid infusion may precipitate serious cardiovascular collapse, arrhythmias, and respiratory depression.</td></tr>
<tr><td>Instructions for preparation and administration:</td><td>For all doses dilute with sodium chloride 0.9% a concentration equivalent to 10mg/mL*, allow for minimal overage, prime the line with the drug then discard excess to avoid potential over infusion.

*Further dilution to 1mg/ml may be necessary for measurability of <u>maintenance doses</u> in particularly small babies.

Give via central access or into a large vein through an in-line filter (0.22–0.50 micron)

• SMART PUMP INSTRUCTION: rate in units mg/kg/minute as above depending on if loading dose/maintenance dose: reduce rate if bradycardia or hypotension occurs (SMART pump allows for a rate 0.45mg/kg/min) in such cases.

• Complete administration within 1 hour of preparation

• Flush with sodium chloride 0.9% before administration.

• After infusion flush with sodium chloride 0.9% at the same rate as drug to reduce irritation and avoid delivering a bolus

Observe syringe for crystallisation and signs of haziness before and during the infusion, do not administer or discontinue infusions showing such an appearance.

Monitor ECG, heart rate and blood pressure during infusion. Observe for signs of respiratory and CNS depression, reduce rate of administration if bradycardia or hypotension occurs. Cardiac resuscitation equipment should be available. Monitor injection site during and for 72 hours following administration.</td></tr>
</table>

	Example for a 3kg baby receiving a loading dose for seizures: - Draw up 1.08mL (54mg) Phenytoin sodium (250mg/5ml injection) - Dilute to 5.4ml of sodium chloride 0.9% to make a concentration of 10mg/ml
Prescribing	Paper chart at RDH MediTech at QHB
Known compatibility issues	**Crystallisation can occur if phenytoin mixes with glucose, therefore flush line with sodium chloride 0.9% before drug administration. After drug administration flush with sodium chloride 0.9% at the same rate as drug.** **See separate compatibility chart.**
Additional Comments:	**Trough levels need to be taken after 7 days** (for steady state to be reached. Be aware that it may take up to 2 weeks in preterm babies.) • Take trough sample immediately prior to 8th day dose • Therapeutic range: Neonate – 3 months: 6 - 15 mg/L (25 - 60 micromol/ L) ➢ Beware that IV phenytoin sodium is not bioequivalent to oral phenytoin preparations, see BNFc or contact a pharmacist.

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

References:

Epanutin® Ready Mixed Parenteral Phenytoin SPC, Pfizer, accessed via https://www.medicines.org.uk/emc/product/57/smpc (last updated 29.5.19) on 4.11.19

BNFc Phenytoin. Accessed: https://bnfc.nice.org.uk/drugs/phenytoin/ on 28/11/23

Medusa Phenytoin Paediatric Monograph. Accessed: https://www.medusaimg.nhs.uk/IVGuideDisplay.asp on 28/11/23

SPC Phenytoin Sodium 50mg/mL Solution for Injection. Accessed: https://www.medicines.org.uk/emc/product/4326/smpc#gref on 28/11/23

Document control sheet

GUIDELINE NUMBER	
AREA IN WHICH THIS MONOGRAPH APPLIES	NICU

DIVISIONAL AUTHORISATION	
GROUP	**DATE**
Paediatric monograph review group	22/12/23

AUTHORS		
Author	Position	Date
Written by:	Lisa Taylor, Paediatric Pharmacist	February 2016
Checked by:	Sharon Conroy, Paediatric Pharmacist	November 2019

If review:

	Position	Date
Reviewed by:	Amanpreet Bria, Shift Working Clinical Pharmacist	November 2023
Checked by:	Lamia Ahmed, Advanced Clinical Pharmacist Women's and Children's	November 2023

Change history:

Changes Reference	Change details	Date
1	NICU information separated from paediatric information by Harriet Hughes, Paediatric Pharmacist and checked by Sharon Conroy	November 2019
2	Monitoring information: - reduce rate of administration if bradycardia or hypotension occurs reduce rate of administration if bradycardia or hypotension occurs	November 2023
3	Example added to support nurses with preparing the drug, flushing instruction added in more detail	December 2023