

Phenobarbital IV and Oral Neonatal

Presentation:	60mg/ml injection
Indication:	Management of neonatal seizures
Dose:	<p><u>LOAD (Intravenous):</u> 1st load: 20 mg/kg infused over 20mins (<i>i.e.</i> rate not exceeding 1mg/kg/minute as per smart pump instruction.)</p> <p>2nd and 3rd load (if required after 20 mins): 10mg/kg infused over 10mins *</p> <p>(i.e. 2 half loads can be administered in addition to the initial full loading dose)</p> <p><i>* If the sum of all loading doses given exceeds 20mg/kg, the maintenance dose should be withheld for 3-4 days, especially if there has been intrapartum asphyxia.</i></p> <p><u>MAINTENANCE:</u> 2.5 – 5 mg/kg once or twice daily (IV or oral) adjusted according to response; starting at least 12-24 hours after the loading dose.</p> <p>The dose is likely to require increasing to twice daily after the first 1-2 weeks of treatment due to liver enzyme induction and reduced plasma half-life.</p>
Route of administration:	<p>IV – administer via central line due to extreme pH and osmolality. If not possible, administer with extreme caution via a large peripheral vein (monitor the site closely for phlebitis).</p> <p>Oral – use alcohol-free liquid or tablets can be crushed and dispersed in water. Contact Pharmacy for further advice if oral route required to ensure alcohol-free preparation obtained</p> <p>(DO NOT GIVE INJECTION VIA ENTERAL ROUTE)</p>

Instructions for preparation:	<p>To make the IV LOADING dose:</p> <p>For all babies, dilute solution with water for injection to make a syringe with a concentration of 20mg/mL.</p> <p>Example if using a 60mg/mL vial for a 3kg baby who requires a 20mg/kg load:</p> <p>Draw up 1mL of 60mg/mL and dilute to 3mL with water for injections, to give a concentration of 20mg/mL and administer over 20minutes. Flush line with sodium chloride at same rate as infusion (9mL/hr)</p> $\text{NB. VTBI (ml)} = \frac{\text{Dose (mg)}}{\text{Concentration (mg per ml)}}$ $\text{* IN THE ABOVE EXAMPLE * } \frac{60\text{mg}}{20\text{mg/ml}} = 3\text{mL}$ <p>To make the IV MAINTENANCE dose:</p> <p>Make a syringe with a concentration of 2.5mg/mL*, to allow for a more accurate dosing/ measurement.</p> <p>E.g. a 3kg baby having a 2.5mg/kg maintenance dose:</p> <p>3kg x 2.5mg = 7.5mg to be administered.</p> <p>Draw up 1mL of 60mg/mL phenobarbital solution for injection and dilute with water for injection to a total volume 24mL (providing a 2.5mg/mL concentration) prime the line, discarding overage and administer 3mL at 1mg/kg/minute. Flush line with sodium chloride 0.9% at same rate as drug infusion.</p> <p style="text-align: center;">** ALWAYS REMOVE ANY EXCESS FROM THE SYRINGE**</p> <p>*Contact Pharmacy if a more concentrated solution is required or for more information. Note SMART pump concentration set at 2.5mg/mL</p>
-------------------------------	--

	<p>For ORAL MAINTENANCE dose:</p> <p>Oral suspension 10mg/ml – supplied by pharmacy on a named patient basis (specify alcohol-free when ordering) Order on the PATIENT SPECIFIC (Temporary Stock) Requisition for Schedule 3 Controlled Drug form found on NET-i</p>
--	---

Directions for administration via SMART pump	<p>Loading Dose</p> <ul style="list-style-type: none"> • Load Syringe, prime line using the pump for accurate dosing • Open 'NICU' folder then open 'phenOBARbital Loading' programme • Enter the Total Volume to be Infused VTBI in mls and confirm • Confirm Total Time of 20mins • Perform STOP moment with medical team (Pump against prescription) • Connect to Baby • Press start button <p>Maintenance Dose</p> <ul style="list-style-type: none"> • Load Syringe, prime line using the pump for accurate dosing • Open 'NICU' folder then open 'phenOBARbital Maint' programme • Enter the Baby's weight in kg and confirm • Enter the Total Volume to be Infused VTBI in mls and confirm • Enter the dose in mg/kg/min and confirm • Visually confirm the rate (ml/h) against the prescribed dose (mg/kg/min) • Perform STOP moment with medical team (Pump against prescription) • Connect to Baby • Press start button
Known compatibility issues	Compatible: Meropenem, morphine sulphate Incompatible: Atracurium, ranitidine Please refer to medusa for further compatibility instructions
Additional Comments:	Approx. time to steady state: 10-14 days but is greatly prolonged in neonates . Plasma-phenobarbital concentration for optimum response is 15–40 mg/litre; however, monitoring the plasma-drug concentration is less useful than with other drugs because tolerance occurs.

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

References:

British National Formulary for Children, accessed via www.medicinescomplete.com 30/11/23

SPC for PHENOBARBITAL accessed via www.medicines.org.uk

Medusa Injectable Medicines Guide, accessed via <http://medusa.wales.nhs.uk>

Trissel LA (Ed), Handbook on Injectable Drugs, accessed via www.medicinescomplete.com

Neonatal Formulary, The Northern Neonatal Network, Phenobarbital

[Leeds Formulary Formulary](http://www.leedsformulary.nhs.uk)

<https://www.leedsformulary.nhs.uk/chaptersSubDetails.asp?FormularySectionID=24&SubSectionRef=24.16&SubSectionID=A100#3633> Accessed 30/11/23

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: Kevin Inglesant	Advanced Pharmacist Women's & Children's	October 2018
Checked by: Harriet Hughes	Specialist Pharmacist Women's & Children's	October 2018

If review:

	Position	Date
Reviewed by: Maisie-Jane Fry and Ellie Cheale Joanna Hurcombe	Specialist pharmacist	November 2023
	Advanced Pharmacist Women's & Children's	30/11/23
Checked by:	Lamia Ahmed Advanced Women's and Children's Pharmacist	December 2023

Change history:

Changes Reference	Change details	Date
	Phenobarbital maintenance concentration changed to allow for measurability with SMART pump	18/02/2020
	Instructions for preparations updated in line with DERS update	18/02/2020
	Clarification or ordering oral Phenobarbital from Pharmacy- updated to new process, sch 3 CD form	30/11/23
	Phenobarbital concentration wording changed from 'no more than 20mg/mL concentration to '20mg/mL' to remove ambiguity and pumps set concertation= 20mg/mL. Changes made to preparation of loading dose to achieve exact drug requirements without any overage.	30/11/23