Ballarat Health Services

Neonatal Drug Guideline

PHENOBARBITONE SODIUM

DESCRIPTION AND INDICATION FOR USE

Phenobarbitone is a long-acting barbiturate with sedative, hypnotic and anti-convulsant properties. It is used in the management of neonatal seizures.

DOSE

IV: **Loading Dose** 15 – 20 mg/kg
May repeat up to maximum 40 mg/kg

IV/PO: **Maintenance Dose*** 3 – 5 mg/kg/DAY in 1-2 doses

*** Commence maintenance dose:**
24 hours after loading dose

Post neonatal period:
If ex-term and >28 days or corrected gestational age > 44/40 refer to AMH Children's Dosing Companion

RECONSTITUTION/DILUTION

Ampoule = 200 mg in 1 mL

IV: 1. Withdraw 1 mL of 200 mg/mL solution
2. Add to 9 mL of sodium chloride 0.9% (total volume = 10 mL)
(concentration = 200 mg in 10 mL = **20 mg/mL**)

Not for IM, subcut use

ROUTE AND METHOD OF ADMINISTRATION

IV: LOADING DOSE: give over 20 minutes by continuous infusion via syringe pump

MAINTENANCE DOSES: give as an IV push at a rate of 1mg/kg/minute or slower
(maximum IV push rate in an emergency: 2 mg/kg/minute)

COMPATIBILITY INFORMATION

Please contact your ward pharmacist for information on drugs or fluids not appearing in the table below. Medications that are not routinely used in the Special Care Nursery have not been included in this table and may be incompatible.

	Compatible	Incompatible
Fluids	Glucose 5%, Sodium chloride 0.9%	
Drugs	Calcium gluconate	Aminophylline, Morphine, Phenytoin, Ranitidine, Vancomycin

SIDE EFFECTS

- Sedation, drowsiness
- Mild skin reactions and thrombophlebitis
- Less common: hypotension, bradycardia, respiratory depression, apnoea, broncho/laryngospasm, hepatitis, jaundice

→ NOTE: Solution for injection contains benzyl alcohol and propylene glycol

SPECIAL PRECAUTIONS

- Caution in patients with severe renal and/or hepatic impairment
- Caution in patients with hypotension and respiratory depression
- Chronic administration may decrease bone mineral density and increase risk of fractures – vitamin D supplementation may be necessary
- Avoid abrupt discontinuation of phenobarbitone following prolonged use

DRUG INTERACTIONS

Phenobarbitone is an enzyme INDUCER, therefore may reduce the effectiveness some co-administered medications. This interaction may take a week or more to develop. Affected medications include:
Aminophylline/Theophylline, Corticosteroids, Digoxin, Metronidazole, Paracetamol

Phenytoin:
Variable effects – concentrations of either or both medications may be altered. Therapeutic drug monitoring of both medications is recommended when both agents are to be used regularly and simultaneously.

Central Nervous System Depressants (eg: midazolam, morphine):
Observe for additive effect on sedation and respiratory depression

NURSING RESPONSIBILITIES

- Observations/Monitoring
  - Therapeutic drug monitoring may be required with this medication. Check if phenobarbitone serum level results need to be acted upon prior to the administration of the next dose. Check the date and time when the next blood level is required (see below)
  - Monitor heart rate and blood pressure
  - Monitor respiratory rate and observe chest movement – be alert for early signs of under ventilation or apnoea. Doses greater than 20 mg/kg may require mechanical ventilation in some neonates.
  - Transcutaneous O_2/CO_2 or oximetry if indicated and requested by Paediatrician/Paediatric Registrar
  - Observe IV site for signs of extravasation and thrombophlebitis
- Visually inspect solution prior to administration – only administer clear solutions, do NOT use solutions with a precipitate, turbidity or if yellow coloured
- Protect from light during storage

- Therapeutic drug monitoring:

  Routine assessment of phenobarbitone levels may not be necessary and the target therapeutic range should be viewed as a guide only. Patients may be seizure free and have serum phenobarbitone levels below the therapeutic range whilst others may require serum levels above the maximum range to achieve seizure control. Likewise, dose-related toxicity may become evident for some patients whose serum levels fall within or even below the therapeutic range, whilst others will not experience toxicity at serum levels above the maximum therapeutic range. Therefore it is important to treat and assess the patient based on their clinical response to the medication rather than rely on the laboratory value to guide therapy.

	Start Monitoring*	Samples Required		Therapeutic Range	
		Trough	Peak	Trough	Peak
Phenobarbitone	5 – 7 days	✔ □ sample immediately pre-dose)	Not necessary	65-170 micromol/L	N/A

* If a loading dose has been given, levels may be sampled earlier to determine if the therapeutic range has been reached or to confirm toxicity, however time to steady state is highly variable and may be up to 9 days or longer in pre-term infants.