# 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/IM:** **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

## RECONSTITUTION/DILUTION

**Ampoule = 200 mg in 1 mL**

**IV**:
1. Withdraw 1 mL of 200 mg/mL solution
2. Add to 1 mL of Water for Injections in a 2 mL syringe (concentration = 200 mg in 2 mL = **100 mg/mL**)
3. Discard excess volume to obtain required dose or withdraw dose using another syringe
4. Further dilute dose with 10 times the volume

**IM**: Use 200 mg/mL solution undiluted

**Not for SC 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** | Dextrose 5%, 0.9% Sodium chloride | |
| **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
  - 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 | 60 – 120 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.