Waikato District Health Board	Type: Drug Guideline	Document reference: 2952	Manual Classification: Waikato DHB Drug Guidelines
Title: **Phenobarbital sodium for neonates**			Effective date: **8 December 2021**
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BRIEF ADMINISTRATION GUIDE

For detailed information refer to The Australasian Neonatal Medicines Formulary **phenobarbital** guideline

Note: phenobarbital = phenobarbitone (names are used interchangeably)

Indication:
- Seizures
- Sedation / irritability

Route: Intravenous, or oral

- Injection supplied as phenobarbital sodium 200 mg in 1 mL ampoule
  - Contains 10% alcohol and 67.8% propylene glycol
  - Is an **unregistered medicine,** available under section 29. Names of patient and doctor prescribing must be sent to Pharmacy when ordering
  - pH of undiluted phenobarbital sodium is 10.5
- Oral liquid supplied as 10 mg/mL (manufactured by Waikato Hospital Pharmacy on an individual patient basis)

Dose:

Loading dose: 20 mg/kg. Additional doses of 10mg/kg may be administered at 30 minute intervals to maximum cumulative dose of 40 mg/kg.
Note: a loading dose may not be necessary if using for sedation

Maintenance dose: 4 mg/kg (range 3-5 mg/kg/dose) every 24 hours, starting 24 hours after the loading dose. Titrate dose for seizure control and therapeutic concentrations.

Note 1: reduce dose if renal or hepatic impairment, or significant asphyxia

Note 2: *the oral dose should initially be the same as the intravenous dose* (but monitor for seizure activity and serum levels, and adjust dose if required)

Note 3: tolerance and dependence may develop with long term use. If therapy is to be stopped phenobarbital should be withdrawn slowly.

Note 4: phenobarbital is associated with numerous drug interactions; monitor all therapy

Serum levels: Monitor serum phenobarbital levels after the loading dose(s) and once patient has reached steady state – after approx. 10 to 14 days (or earlier if indicated), then as required.
Measure trough level just prior to next dose.
Therapeutic plasma levels for optimum response (seizures): 65-170 micromol/L.
Note: monitoring plasma-drug concentration is less useful than with other drugs because tolerance occurs

Preparation and administration:

Compatible fluids: glucose 5%, glucose 10%, sodium chloride 0.9%, glucose 5% and sodium chloride 0.9%

Intravenous

- Draw up 1 mL of phenobarbital sodium and add 9 mL of water for injection to make a final concentration of 200mg/10mL = **20 mg/ml**
- If necessary this solution can be diluted further with compatible fluid
- Infuse **loading dose** over **20 minutes** via Guardrail profiled syringe driver, preferably via a CVAD if possible (as solution is irritant)
- Administer **maintenance** dose over at least **5 minutes** by slow IV injection
  Note: risk of respiratory depression, blood pressure irregularities, apnoea and circulatory collapse with rapid administration
- Do not mix with any other medications (unless approved by Pharmacy)

Oral

- Draw up prescribed dose of oral solution in an oral syringe
- Give immediately before or with feeds to minimise gastric irritation
  Note: Ensure consistency with administration in relation to food

Monitoring

- Continuous cardiorespiratory monitoring during infusion
- Document vital signs hourly and when required
- Watch for signs of hypersensitivity and adverse effects (especially skin rashes)
- Monitor seizure activity: frequency, duration and severity (if using for this indication)
- Observe injection site for signs of irritation/phlebitis(extravasation can lead to tissue necrosis)
- Check liver function periodically

Storage and Stability

- Discard any unused solution in the ampoule after opening
- Oral solutions are stable for up to 30 days from manufacture at room temperature

Competency for Administration

This procedure is carried out by, or under, the direct supervision of a registered nurse/registered midwife who holds current Waikato DHB Generic Medicine Management and IV certification plus Guardrails competency (if administering IV) as well as Neonatal specific competency NCV/NAC (if administering via CVAD).

Guardrails Information

Phenobarbital is Guardrail profiled on the CC pump for NICU. Following are the guardrail limits:

Guardrails Drug Name	**Phenobarbital***
Concentration (mg/mL)	
Minimum	5
Maximum	20
Administration Rate (mg/kg/hr)	
Default	60
Soft minimum	30
Soft maximum	61
Hard maximum	61

References

- Australasian Neonatal Medicines Formulary. Phenobarbital Drug Guideline. 2021. Available from: https://www.seslhd.health.nsw.gov.au/sites/default/files/groups/Royal_Hospital_for_Women/Neonatal/Neomed/neomed21phenobarbital.pdf
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