



MONOGRAPH

Phenobarbital

Scope (Staff):	Medical, Pharmacy, Nursing
Scope (Area):	All Clinical Areas

Child Safe Organisation Statement of Commitment

CAHS commits to being a child safe organisation by applying the National Principles for Child Safe Organisations. This is a commitment to a strong culture supported by robust policies and procedures to reduce the likelihood of harm to children and young people.

This document should be read in conjunction with this [DISCLAIMER](#)

! HIGH RISK MEDICINE !

QUICKLINKS

Dosage/Dosage Adjustments	Administration	Compatibility	Monitoring
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DRUG CLASS

Antiepileptic¹

Phenobarbital is a [High Risk Medicine](#).

INDICATIONS AND RESTRICTIONS

- Status epilepticus and all forms of epilepsy except typical absence seizures.³
- Analgesia and Sedation in Paediatric Critical Care.⁴
- Use in Hepatobiliary Iminodiacetic Acid Scan (HIDA).⁵

CONTRAINDICATIONS

- Hypersensitivity to phenobarbital or any component of the formulation
- History of porphyria, either acute intermittent or variegata⁶
- Hypersensitivity to barbiturates or the excipients in the tablets⁶
- Severe anaemia (if it is due to folate deficiency)⁶
- Severe respiratory depression or pulmonary insufficiency⁶

- Severe asthma (if uncontrolled)⁶
- Diabetes mellitus (if uncontrolled)⁶
- A history of drug abuse or dependence⁶
- Severe hepatic or renal impairment⁶
- Sleep apnoea⁶
- Hyperkinetic children⁶
- Severe depression or suicidal tendencies⁶
- Acute or chronic pain (paradoxical excitement may result or other symptoms may be masked)⁶

PRECAUTIONS

- Anaemia, cardiac disease, depression, hyperthyroidism, hypoadrenalism, respiratory depression⁶
- CNS depression which may impair physical or mental ability ²
- Hypersensitivity (exfoliative dermatitis and Stevens-Johnson syndrome) discontinue if dermatological reactions occur²
- Paradoxical stimulatory response (may cause paradoxical responses, including agitation and hyperactivity, particularly in patients with acute or chronic pain and paediatric patients)²
- Respiratory depression (may cause respiratory depression particularly when administered intravenously); use with caution in patients with respiratory disease, including status asthmaticus²
- Phenobarbital should not be used in women of childbearing potential unless the potential benefit is judged to outweigh the risks following consideration of other suitable treatment options⁶
- Toxicities due to propylene glycol have been reported including hyperosmolarity, lactic acidosis, seizures, and respiratory depression (see Formulation section)²
- Additional respiratory support may be required particularly when maximising loading dose or if on concurrent sedative therapy
- Repeat doses administered sooner than 10 to 15 minutes may not allow adequate time for peak CNS concentrations to be achieved and may lead to CNS depression.²

FORMULATIONS

Listed below are products available at PCH, other formulations may be available, check with pharmacy if required:

- Phenobarbital 10 mg/mL Elixir (Auspman®)⁷
 - Oral Liquid contains ethanol 10.8% v/v

- Phenobarbital 200 mg/mL Ampoule⁷
 - Injection contains propylene glycol and ethanol.
- Phenobarbital 30 mg Tablet⁷

Imprest location: [Formulary One](#)

DOSAGE & DOSAGE ADJUSTMENTS

Neonates: [Refer to Neonatal Medication Protocols](#)

Focal (partial) seizures, generalised tonic-clonic seizures:

Oral / Intravenous

- 4 weeks – 12 years: Initially 1–2 mg/kg daily in 1 or 2 doses. If necessary, increase gradually, according to response and plasma phenobarbital concentration, to usual maintenance dose of 3–6 mg/kg daily in 1 or 2 doses. Up to 8 mg/kg daily may be required.⁸
- 12–18 years: initially 30 mg at bedtime. If necessary, increase gradually up to 240 mg daily in 1 or 2 doses.⁸

Status epilepticus:

Intravenous/ Intraosseous

- 4 weeks – 18 years: 15–20 mg/kg (maximum 1 g)^{8,9}
- consider reducing the dose, e.g., to 5–10 mg/kg, for children already taking phenobarbital.⁸

If a loading dose has been given, maintenance dosing is usually started 12 hours later.⁸

Paediatric Critical Care (PCC) Sedation:

- Sedation of intubated patients -Initial IV loading dose: 5-10 mg/kg (max 200 mg). Can repeat up to 60 mg/kg in 24 hours (max 1g).^{2,4, 9,10}
- Regular dosing - IV/Enteral: up to 6 mg/kg/DAY in 2-3 divided doses (maximum 100 mg/DAY).^{4,9}

Hepatobiliary Iminodiacetic Acid Scan (HIDA):

- Oral: 5 mg/kg/DAY in 2 divided doses for 5 days (neonate and infants)⁵
- Aim to achieve a serum phenobarbital level of ≥ 15 microgram/mL.⁵

Renal impairment:

- [eGFR calculator](#)
- Maintenance dose post loading:
 - GFR \geq 10 mL/min: No adjustment necessary²
 - GFR < 10 mL/min: decrease dose by 50% and administer every 24 hours²

Hepatic impairment:

- There are no specific dosage adjustments provided in manufacturer's labelling.
- Phenobarbital exposure is increased with hepatic impairment; reduced doses are recommended; use with caution^{1, 9}

RECONSTITUTION AND ADMINISTRATION

- Reconstitution not required, must be diluted before IV use.
- Rapid administration may cause respiratory depression and circulatory collapse¹⁰
- Dilute to 20 mg/mL and infuse over 20 minutes for status epilepticus, or over at least 30 minutes for all other indications.^{2,11}
- The maximum concentration for a fluid restricted patient is 130 mg/mL¹⁰
- Additional respiratory support may be required when using high and/or repeated loading doses, or if given in combination with other antiseizure medications⁹
- Resuscitation and artificial ventilation equipment must be readily available⁵
- Phenobarbital injection is a vesicant; tissue necrosis may result from extravasation^{6,10}
- Avoid small veins. Do not administer intra-arterially⁶
- Monitor the injection site. If the patient complains of pain at the infusion site, or if there are signs of extravasation stop the injection or infusion and take immediate action.¹⁰
- Do not use any solution that has any precipitate or discolouration⁴

COMPATIBILITY (LIST IS NOT EXHAUSTIVE)**Compatible fluids:**

Glucose 5%, glucose 10%, glucose in sodium chloride solution, sodium chloride 0.45%, sodium chloride 0.9%, Hartmann's, Ringer's¹ (for patients at risk of cerebral oedema avoid glucose solutions if possible)¹¹

Compatible at Y-site: Contact pharmacy for information

Only commonly used drugs are listed below. This is not a complete list of incompatible drugs.

[Compatibilities of IV drugs](#) must be checked when two or more drugs are given concurrently.

INCOMPATIBLE drugs:

Adrenaline (epinephrine) hydrochloride, aminophylline, amiodarone, atracurium, benzylpenicillin, caspofungin, cefotaxime, cefoxitin, ciclosporin, clindamycin, dobutamine, ephedrine sulphate,

erythromycin, esmolol, haloperidol lactate, hydralazine, hydrocortisone sodium succinate, hydromorphone, ketamine, lidocaine, midazolam, mycophenolate mofetil, noradrenaline (norepinephrine), ondansetron, pentamidine, pethidine, phentolamine, prochlorperazine mesilate, promethazine, protamine, pyridoxine, suxamethonium, thiamine, verapamil¹¹

MONITORING

During administration

IV use: Respiratory rate, heart rate, blood pressure, IV site (stop injection if any evidence of pain, swelling, discoloration, or temperature change in the limb)¹

- Continuous heart rate and oxygen saturation monitoring for the duration of infusion and 30 minutes following the infusion
- Assess respiratory rate and blood pressure every 5 minutes for duration of infusion and 30 minutes following the infusion
- Equipment for resuscitation and artificial ventilation must be readily available¹

Therapeutic drug monitoring

Timing of serum samples: Draw trough just before next dose²

- Target trough level: 10-40 **microgram/mL**²
- A clear correlation between serum phenobarbital concentrations and therapeutic response has not been demonstrated¹
- Time to steady state without loading dose: 2-4 weeks¹

Additional monitoring

CNS status, seizure activity, liver enzymes (periodic with prolonged therapy)²

With prolonged therapy: complete blood count, renal function, vitamin D levels, signs, and symptom of suicidality (anxiety, depression, behaviour changes)²

ADVERSE EFFECTS

Common: Sedation, confusion, depression, allergic skin reactions, cholestasis, cognitive impairment, impaired memory, irritability, lethargy, altered mood and behaviour, hallucinations, paradoxical insomnia, hyperactivity and aggression, hypotension (IV) and respiratory depression (IV)¹

Infrequent: Decreased bone mineral density (long-term use), nystagmus, ataxia, hyperkinesia²

Rare: Exfoliative dermatitis, multiorgan hypersensitivity syndrome, Stevens-Johnson syndrome, toxic epidermal necrolysis, megaloblastic anaemia, Dupuytren's contracture, frozen shoulder, osteomalacia, agranulocytosis, thrombocytopenia, hepatitis, suicidal ideation²

STORAGE

Protect from light. Store below 25°C⁴

INTERACTIONS

This medication may interact with other medications; consult PCH approved references (e.g. [Clinical Pharmacology](#)), a clinical pharmacist or PCH Medicines Information Service on extension 63546 for more information.

Please note: The information contained in this guideline is to assist with the preparation and administration of **phenobarbital**. Any variations to the doses recommended should be clarified with the prescriber prior to administration

Related CAHS internal policies, procedures and guidelines

[High Risk Medications – CAHS Policy Manual Medication Management and Pharmacy](#)

[Seizure Medication - PCH Emergency Department](#)

[Status Epilepticus – PCH Emergency Department](#)



References

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2. Up To Date PCH Library [Internet] [Phenobarbital: Pediatric drug information - UpToDate \(health.wa.gov.au\)](#)
3. British National Formulary (BNF for Children) [Internet] [MedicinesComplete — BNF for Children > Drug: Phenobarbital \(health.wa.gov.au\)](#)
4. PCC Sedations – Expert opinion [Analgesia and Sedation in Paediatric Critical Care \(health.wa.gov.au\)](#)
5. Phenobarbital-enhanced hepatobiliary scintigraphy in the diagnosis of biliary atresia: two decades of experience at a tertiary centre Pediatric Radiology 43 1365-1375 (2013) N Kwatra E Shalby-Rana, S Narayanan, P Mohan, S Ghelani, M Majd
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7. Formulary ONE - Health point [Internet] via Health Applications [Paediatric - WA Statewide Medicines Formulary \(health.wa.gov.au\)](#)
8. Australian Medicines Handbook, Pharmaceutical Society of Australia, Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists, Royal Australian College of General Practitioners. AMH children's dosing companion (AMH –CDC [Internet] _ [Phenobarbital - AMH Children's Dosing Companion \(health.wa.gov.au\)](#)
9. Bennett PN, Brown MJ, Sharma P, Elsevier. Clinical pharmacology [Internet]. 11th ed. Edinburgh: Churchill Livingstone/Elsevier; 2013 [cited. Available [Phenobarbital Monograph - Clinical Pharmacology \(health.wa.gov.au\)](#)

References

10. AHFS Drug Information, [PHENobarbital, PHENobarbital Sodium \(Sedative\) - TDS Health](#)
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Compassion

Excellence

Collaboration

Accountability

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Respect

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