South Australian Neonatal Medication Guidelines

Phenobarbital

200mg/mL injection, 3mg/mL oral mixture

Note:

This guideline provides advice of a general nature. This statewide guideline has been prepared to promote and facilitate standardisation and consistency of practice, using a multidisciplinary approach. The guideline is based on a review of published evidence and expert opinion.

Information in this statewide guideline is current at the time of publication.

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Health practitioners in the South Australian public health sector are expected to review specific details of each patient and professionally assess the applicability of the relevant guideline to that clinical situation.

If for good clinical reasons, a decision is made to depart from the guideline, the responsible clinician must document in the patient's medical record, the decision made, by whom, and detailed reasons for the departure from the guideline.

This statewide guideline does not address all the elements of clinical practice and assumes that the individual clinicians are responsible for discussing care with consumers in an environment that is culturally appropriate and which enables respectful confidential discussion. This includes:

- The use of interpreter services where necessary,
- Advising consumers of their choice and ensuring informed consent is obtained,
- Providing care within scope of practice, meeting all legislative requirements and maintaining standards of professional conduct, and
- Documenting all care in accordance with mandatory and local requirements

This is a High Risk Medication ⚠

An overdose can be rapidly fatal.

Synonyms

Phenobarbitone

Dose and Indications

Anticonvulsant

Intravenous Loading Dose

Start at 20mg/kg/dose administered over 20 minutes. If no response, additional doses (10mg/kg) may be administered at 30 minute intervals (maximum cumulative load of 40mg/kg).

Ventilation may be required, especially if more than 1 dose is given.

Intravenous or Oral Maintenance Dose

5mg/kg once a day, commencing 24 hours after the loading dose.

Neonatal Abstinence Syndrome

Oral

This guideline MUST be used in conjunction with the South Australian Perinatal Practice Guidelines – Infants of drug dependent women

Loading dose of 15mg/kg followed 12 hours later by a maintenance dose of 5 mg/kg once daily. Wean as per neonatologist advice.

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Preparation and Administration

Intravenous

Add 1mL (200mg) of phenobarbital injection to 9mL of compatible fluid (to a total volume of 10mL). Shake gently to mix. The resulting solution contains 20mg/mL phenobarbital

Example Doses:

Dose	6mg	12mg	18mg	24mg	30mg	36mg	42mg	48mg	54mg	60mg
Volume	0.3mL	0.6mL	0.9mL	1.2mL	1.5mL	1.8mL	2.1mL	2.4mL	2.7mL	3mL

Discard unused solution

Administer loading dose slowly over 20 minutes. Maximum intravenous rate is 1mg/kg/minute.

Oral

The oral solution contains 3mg/mL phenobarbital.

Example Doses:

Dose	3mg	6mg	9mg	12mg	15mg	18mg	21mg	24mg	27mg	30mg
Volume	1mL	2mL	3mL	4mL	5mL	6mL	7mL	8mL	9mL	10mL

Give with feeds to minimise gastric irritation.

Compatible Fluids

Glucose 5%, glucose 10%, glucose/sodium chloride solutions, sodium chloride 0.9%

Adverse Effects

Prolonged use may cause physical dependence.

Common

Sedation, rash and paradoxical insomnia, hyperactivity and irritability. Hypotension and respiratory depression are more likely with intravenous therapy.

Infrequent

Nystagmus, ataxia

Rare

Megaloblastic anaemia, exfoliative dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis, multi-organ hypersensitivity syndrome, osteomalacia. Skin necrosis (extravasation) with IV
Hypersensitivity reactions are not commonly seen in neonates

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Monitoring

- When this medication is given regularly as an anticonvulsant, Therapeutic Drug Monitoring is recommended.
- It will take several (2 to 3) weeks to achieve steady state unless a loading dose is given
- Trough levels are recommended (prior to next dose). The therapeutic range is between 45 and 130micromol/L.
- The recommended therapeutic range of phenobarbital is higher in the neonatal period than in children and adults

Practice Points

- Assisted ventilation may be required during intravenous injection and should be available when giving via this route
- Do not use any solution which has a precipitate or discolouration
- IM administration is associated with poor absorption and tissue damage while subcutaneous administration is associated with tissue necrosis. The solution is highly alkaline. Neither route is recommended
- The ampoule contains 83mg/mL ethanol and 700mg/mL propylene glycol
- The elixir contains 9.6% ethanol
- Do not use in patients with acute porphyria
- Use with CAUTION in patients with severe hepatic or renal impairment, respiratory depression, asphyxia or therapeutic hypothermia as half-life may be prolonged
- Phenobarbital use can be associated with electro-clinical dissociation of seizures
- Phenobarbital interacts with a range of medications; please check with your local pharmacy department for specific advice

Document Ownership & History

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