#### South Australian Neonatal Medication Guidelines

# phenobarbitone

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

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#### 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 1

An overdose can be rapidly fatal.

#### Checklist

Before administering a dose:

- > Check if phenobarbitone serum level results need to be acted upon prior to the administration of the next dose;
- Check if the dose or dosing interval needs amendment as a result of the blood level results;
- > Check the date and time when the next blood level is required; and
- > Document the ongoing plan in the Nursing Care Plan and/or Medication Chart

## **Synonyms**

Phenobarbital sodium

**ISBN number:** 978-1-74243-422-3

**Endorsed by:** South Australian Maternal & Neonatal Clinical Network

**Last Revised:** 8/11/2012

Contact: South Australian Neonatal Medication Guidelines Workgroup at:

NeoMed@health.sa.gov.au



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### **Dose and Indications**

#### **Anticonvulsant**

#### **Intravenous or Oral Loading Dose**

Start at 20mg/kg/dose administered over 20 minutes. For ventilated patients repeat doses of 20mg/kg every 20 minutes to a total of 80mg/kg if required for seizure control.

#### **Intravenous or Oral Maintenance Dose**

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

#### **Neonatal Abstinence Syndrome**

#### Oral

Loading dose of 10mg/kg followed 12 hours later by a maintenance dose 5 mg/kg once daily. Wean as per neonatologist advice.

Refer the South Australian Perinatal Practice Guidelines.

## **Preparation and Administration**

#### Intravenous

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

Dose	4mg	8mg	12mg	16mg	20mg
Volume	0.2mL	0.4mL	0.6mL	0.8mL	1mL

Discard unused solution

Administer slowly over 20 minutes. Maximum intravenous push rate (in emergency) is 2mg/kg/minute.

#### Oral

The oral solution contains 3mg/mL phenobarbitone.

Dose	3mg	6mg	9mg	12mg	15mg
Volume	1mL	2mL	3mL	4mL	5mL

Give with feeds to minimise gastric irritation.

## Compatible Fluids

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

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### **Adverse Effects**

Prolonged use may cause physical dependence.

#### Common

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

#### Infrequent

Nystagmus, ataxia

#### Rare

Megaloblastic anaemia, skin necrosis (extravasation), spasm and pain particularly with intravenous use.

Hypersensitivity reactions are not commonly seen in the neonates

## 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 65 and 170micromol/L
- The recommended therapeutic range of phenobarbitone 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 benzyl alcohol, propylene glycol, sodium hydroxide and/or hydrochloric acid
- > The elixir contains less than 10% ethanol
- > Do not use in patients with acute porphyria
- Use with CAUTION in patients with severe hepatic or renal impairment, hypotension or respiratory depression or asphyxia as half-life may be prolonged
- > Phenobarbitone has been used for hyperbilirubinaemia
- > Phenobarbitone interacts with a range of medications; please check with your local pharmacy department for specific advice

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## Version control and change history

PDS reference: OCE use only

Version	Date from	Date to	Amendment
1.0	November 2012	current	Original version

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