



## NEONATAL MEDICATION GUIDELINE

# Phenytoin Sodium

**Scope (Staff):** Nursing, Medical and Pharmacy Staff

**Scope (Area):** KEMH NICU, PCH NICU, NETS WA

This document should be read in conjunction with the [Disclaimer](#).

### Quick Links

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### Restrictions

[Formulary: Highly Restricted](#)

Requires Neonatologist or Neurologist approval before commencing

**HIGH RISK Medication** ⚠️

An overdose can be rapidly fatal. Increases in doses must be in small increments (10%) because metabolism of phenytoin is saturable and rate-limited. Small dosage adjustments may result in large changes in free serum phenytoin levels

### Description

Anticonvulsant

### Presentation

**Ampoule:** 50mg/mL – phenytoin sodium (2mL or 5mL volumes)

**Oral solution:** 100mg/5mL

### Storage

Store at room temperature, below 25°C

Protect from light

### Contraindications

Hypersensitivity to phenytoin or any components of the formulation

Acute porphyrias

Sinus bradycardia, sinoatrial clock, second and third degree atrioventricular block, Stokes-

Adams Syndrome – IV phenytoin contraindicated

## Dose

Formulations of phenytoin are available as phenytoin base or phenytoin sodium. Doses below are prescribed as phenytoin sodium

100mg phenytoin sodium = 90mg phenytoin base

Consider concentration monitoring when changing from a product containing phenytoin to another product containing phenytoin sodium (and vice versa); adjust dosage as necessary

## Control of seizures unresponsive to first line therapy

**IV/Oral:**

**Loading dose:** 15 – 20 mg/kg

**Maintenance dose:** 2 – 4 mg/kg/dose every 12 hours

**Maximum:** 8 mg/kg/dose every 8 to 12 hours after 1 week of age

## Dose Adjustment

Dosage should be individualised based upon clinical response and serum concentration

**Renal & Hepatic Impairment:**

Dose adjustment may be required in severe hepatic and renal impairment

## Preparation

**IV**

Can be used undiluted at a concentration of [50mg/mL](#)

**Note:** diluted phenytoin may precipitate over time, inspect solutions for infusions carefully. Do not use if precipitation or haziness occurs

Dilute 1mL (50mL) of phenytoin sodium to a final volume of 10mL with Sodium Chloride 0.9%

Concentration = 50mg/10mL = [5mg/mL](#)

## Administration

**IV**

Flush the line with Sodium Chloride 0.9% before and after administration

Administer into a large vein where possible through a large gauge catheter

Diluted phenytoin may precipitate – it is recommended to infuse through a 0.22 micron filter

**The rate of intravenous phenytoin administration should not exceed 1 – 3 mg/kg/minute or 50mg/minute, whichever is slower**

Faster infusions increase the risk of severe hypotension and cardiac arrhythmias

Careful cardiac monitoring is needed during and after administering intravenous phenytoin – see *Monitoring* section

## Compatible Fluids

Sodium Chloride 0.9%

## Y-Site Compatibility

Refer to KEMH Neonatal Medication Guideline: [Y-Site IV Compatibility in Neonates](#)

## Side Effects

**Common:** CNS depression, bradycardia, hypotension, feed intolerance, can cause vein irritation and tissue necrosis

**Serious:** cardiovascular collapse, rash, blood dyscrasias

## Interactions

Incompatible with Glucose 5%

Do not mix with any other medication or fluids

## Monitoring

Monitor electrocardiogram, blood pressure, and respiratory function continuously during infusion, and for 15 minutes to 1 hour after infusion. Observe IV site for extravasation. Follow serum concentration closely

### Drug levels

**Sampling time:** Just before next dose (trough)

Phenytoin elimination half-life is variable and steady-state may not yet be reached (can take up to 7 – 10 days) in the initial serum samples

Take initial concentration **48 hours** after loading dose and then weekly if continued on phenytoin therapy

**Therapeutic range *in the first week*:**

6 – 15 microgram/mL (highly variable)

**Therapeutic range *after steady state*:**

10 – 20 microgram/mL due to changes in protein binding

**Comments**

Oral absorption is poor, varying response seen in the first week of life

A small change in dosage may result in a disproportionately large change in phenytoin concentration due to saturation of its hepatic metabolism

Use with caution in infants who have received lidocaine – increased risk of cardiotoxicity

**Related Policies, Procedures & Guidelines****CAHS Clinical Practice Guidelines:**

[Neonatal Seizures](#)

[NETSWA: Seizures](#)

[Medication Administration: Intramuscular, Subcutaneous, Intravascular](#)

**References**









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Keywords	Phenytoin, epilepsy, seizures				
Document Owner:	Head of Department - Neonatology				
Author/ Reviewer	KEMH & PCH Pharmacy/Neonatology Directorate				
Version Info:	Updated template, amended links				
Date First Issued:	March 2008	Last Reviewed:	10/07/2020	Review Date:	10/07/2023
Endorsed by:	Neonatal Directorate Management Group			Date:	July 2020
NSQHS Standards Applicable:	<input checked="" type="checkbox"/>  Std 1: Clinical Governance <input type="checkbox"/>  Std 2: Partnering with Consumers <input checked="" type="checkbox"/>  Std 3: Preventing and Controlling Healthcare Associated Infection <input checked="" type="checkbox"/>  Std 4: Medication Safety		<input type="checkbox"/>  Std 5: Comprehensive Care <input type="checkbox"/>  Std 6: Communicating for Safety <input type="checkbox"/>  Std 7: Blood Management <input checked="" type="checkbox"/>  Std 8: Recognising and Responding to Acute Deterioration		
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