NEONATAL Medication Monograph

PHENYTOIN SODIUM

This document should be read in conjunction with this **DISCLAIMER**

Highly Restricted: Requires Neonatologist or Neurologist approval before commencing

⚠ HIGH RISK Medication

⚠ An overdose can be rapidly fatal. Increases in dose 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.

Presentation	Ampoule: 50mg/mL – phenytoin sodium (2mL or 5mL volumes) Oral Solution: 100mg/5mL
Description	Anticonvulsant
Indications	Control of seizures unresponsive to first line therapy
Contraindications	• Hypersensitivity to phenytoin or any components of the formulation • Acute porphyrias • Sinus bradycardia, sinoatrial block, second and third degree atrioventricular block, Stokes-Adams Syndrome – IV phenytoin contraindicated
Precautions	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
Dosage	Formulations of Phenytoin are available as phenytoin base or phenytoin sodium Doses below are prescribed as **phenytoin sodium** 100mg of phenytoin sodium = 90mg of phenytoin Consider concentration monitoring when changing from a product containing phenytoin to another product containing phenytoin sodium (and vice versa); adjust dosage as necessary
	IV/Oral: **Loading Dose**: 15mg/ kg to 20mg/ kg **Maintenance Dose:** 2 to 4mg/ kg/ dose every 12 hours **Maximum** 8mg/ kg/ dose every 8 to 12 hours after 1 week of age

Dosage Adjustment	Dosage should be individualised based upon clinical response and serum concentration Dose adjustment may be required in severe hepatic and renal impairment
Adverse Reactions	**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 was any other medication or fluids
Compatible Fluids	Sodium Chloride 0.9% **ONLY**
Preparation	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 (50mg) of phenytoin sodium to a final volume of 10mL with Sodium Chloride 0.9% Concentration is 50mg/10mL = **5mg/mL**
Administration	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 0.22micron inline filter **The rate of intravenous phenytoin administration should not exceed 1 to 3 mg/ kg/ minute or 50 mg/ minute, whichever is slower.** Faster infusions increase the risk of risk of severe hypotension and cardiac arrhythmias. Careful cardiac monitoring is needed during and after administering intravenous phenytoin. See ***Monitoring*** details below

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 to 15 mcg/mL (highly variable) **Therapeutic range after steady state:** 10 to 20mcg/mL due to changes in protein binding
Storage	Store below 25°C. Protect from light
Notes	Oral absorption is poor, varying response seen in the first week of life .
Related clinical guidelines	Seizures: Neonatal NETSWA: Seizures
References	Lilley L, Legge D. Paediatric injectable guidelines. 5th ed. Melbourne (Victoria): The Royal Children's Hospital; 2019. Takemoto CK, Hodding JH, Kraus DM. Pediatric & neonatal dosage handbook with international trade names index : a universal resource for clinicians treating pediatric and neonatal patients. 24th ed. Hudson (Ohio): Lexicomp; 2019 Truven Health Analytics. Phenytoin. In: NeoFax [Internet]. Greenwood Village (CO): Truven Health Analytics; 2020 [cited 2020 Apr 11]. Available from: https://neofax.micromedexsolutions.com/ Society of Hospital Pharmacists of Australia. Buprenorphine. In: Australian Injectable Drugs Handbook [Internet]. [St Leonards, New South Wales]: Health Communication Network; 2020 [cited 2020 Apr 11]. Available from: http://aidh.hcn.com.au British National Formulary. BNF for Children. 2018-19 ed. London, UK: BMJ Group and Pharmaceutical Press; 2018.

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