REGIONAL PEDIATRIC PARENTERAL DRUG MONOGRAPH

GENERIC NAME

PHENobarbital

Effective Date: May 2013 Revised Date: Nov13-2013	CLASSIFICATION **Anticonvulsant** **Sedative/Hypnotic**	OTHER NAMES **Phenobarb**	PAGE 1 of 3

ADMINISTRATION POLICY:

IV Bolus - May be administered by a nurse
IM Injection - May be administered by a nurse
Umbilical Artery Catheter (UAC) - Administration restricted to physicians
Subcutaneous - Not recommended

RECONSTITUTION/DILUTION/ADMINISTRATION:

Supplied as: 120 mg/1 mL ampoules

EXTRAVASATION ALERT: Phenobarbital injection is very alkaline

Direct: Preferred route of IV administration
Administer into an infusing IV solution over 3 to 5 minutes. Do not exceed maximum rate.

Intermittent: Dilute in compatible IV solution and infuse over at least 10 to 20 minutes

Central: No special considerations. Refer to Direct or Intermittent.

Intramuscular: Absorption by IM route is slow and erratic. Inject into large muscle mass due to alkaline pH. Use needle gauge and length appropriate for age.

Umbilical Artery Catheter (UAC): No special considerations. Refer to Direct or Intermittent.

Maximum Rate:
IV Newborn: 2 mg/kg/minute
Children, Adolescents: 1 mg/kg/minute (maximum 60 mg/minute)

Maximum Concentration:
IV 30 mg/mL
IM 120 mg/mL

DOSAGE:

Status Epilepticus, Seizure Disorders

IV	**Load:**	Neonates	15-20 mg/kg
		Infants >30 days, children	10-20 mg/kg
		Adolescents	5-10 mg/kg/dose (usual: 120 mg/dose) (usual maximum total dose: 400-600 mg)

Repeat 5-10 mg/kg/dose every 20-30 minutes until seizure stop, serum concentration of 40 mg/L is attained, or 40 mg/kg/total dose (rarely, up to 60 mg/kg/total dose).

(Dosage continued)

DOSAGE (continued):

IV, IM **Maintenance:** Start 12 to 24 hours after initial loading dose

Neonates (asphyxiated or <1 kg)	2-5 mg/kg/24 hours divided every 12 to 24 hours
Neonates	5 mg/kg/24 hours divided every 12 to 24 hours
Infants >30 days, children	3-5 mg/kg/24 hours divided every 12 to 24 hours
Adolescents	2-4 mg/kg/24 hours divided every 12 to 24 hours (usual: 60-120 mg/dose)

Drug Withdrawal, Sedation, Procedural Sedation

IV **Load:** as above, if indicated

IV, IM **Maintenance:** Start 12 to 24 hours after initial loading dose

Neonates, Infants, Children	8-15 mg/kg/24 hours divided every 6 to 8 hours Goal serum concentration: 35-45 mg/L
Adolescents	3-5 mg/kg/dose every 6 to 8 hours

Renal Impairment: Use same loading dose. For maintenance dose, start with lower end of dosage range.

Hepatic Impairment: Use same loading dose. For maintenance dose, start with lower end of dosage range.

Obesity: Loading dose: use total body weight. Maintenance dose: use lean body weight.

STABILITY/COMPATIBILITY:

Stability of Open Ampoule: Discard unused portion

Stability of Final Admixture: 24 hours at room temperature

Compatibility: D5W, D10W, Normal Saline, dextrose-saline combinations

IM, SC: Do not mix with other medications in same syringe.

PRECAUTIONS, POTENTIAL ADVERSE REACTIONS:

CV: hypotension (with rapid IV administration)

NEURO: drowsiness, lethargy, paradoxical excitation

RESP: respiratory depression and apnea (especially with rapid IV administration)

LOCAL: extravasation risk – pain at injection site necrosis
Avoid intra-arterial injection – spasms, severe pain, discolored or cyanosed skin

OTHER: rash
hyperosmolality, cardiac arrest and refractory seizures (secondary to high dose of propylene glycol)

(precautions, potential adverse reactions continued)

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PRECAUTIONS, POTENTIAL ADVERSE REACTIONS (continued):
CAUTION:

- Pre-existing CNS depression
- Severe uncontrolled pain (increased risk of respiratory depression)
- Intermittent porphyria
- Severe respiratory disease with dyspnea or obstruction
- Nephritis
- Hepatic disease
- Neonates or patients (any age) with renal impairment: products contain benzyl alcohol and propylene glycol which may produce toxicity (metabolic acidosis, respiratory distress, hyperosmolality).

CONTRAINDICATIONS:

- Hypersensitivity to Phenobarbital or any of the excipients

REQUIRED MONITORING:

Loading Dose: Monitor blood pressure and respiratory rate at baseline, end of infusion and 15 minutes post-infusion