West of Scotland NEONATAL Parenteral Drug Monographs

Phenobarbital - Phenobarbitone

FORM Ampoule containing 60mg in1ml

INDICATION 1. Control of neonatal seizures.

2. Sedation in Neonatal abstinence syndrome.

DOSE RANGE

Indication 1. Control of neonatal seizures.

AGE	DOSE	FREQUENCY	ROUTE
Neonate	20mg/kg/dose	Single *	IV
Loading			
Maintenance**	2.5 - 5mg/kg/dose	1 dose daily	IV

^{*}LOADING DOSE give 20mg/kg (given over 20minutes) if baby fitting. If fitting persists, give another 10mg/kg (given over 10 minutes) after 20 minutes. If fitting persists, a final 10mg/kg (given over 10 minutes) should be given after a further 20 minutes. Maximum total loading dose 40mg/kg. Care required as apnoea may be a problem.

Indication 2. Sedation in Neonatal abstinence syndrome.

AGE	DOSE	FREQUENCY	ROUTE	
Neonate Loading	15mg/kg/dose	Single	IV	
Maintenance commenced 24	8mg/kg/dose	1 dose daily	IV	
hours after loading dose				

RECONSTITUTION	Already in solution – must be diluted prior	to use	
DILUTION	Phenobarbital injection (60mg in 1ml) Water for injection Gives 10mg in 1ml solution for IV use. Use	1ml up to 6ml total e required volume.	
	For loading dose for babies >2.3kg use:		
	Phenobarbital injection(60mg in 1ml) Water for injection Gives 10mg in 1ml solution for IV use. Use	2ml up to 12ml total e required volume.	
METHOD OF ADMINISTRATION	For IV administration to be given slowly at 1mg/kg/minute.	a maximum rate of	

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^{**} see Neonatal seizures policy. Maintenance phenobarbital only to be used on direction of a Consultant Paediatrician. Maintenance dose commences 24 hours after loading dose.

^{*}Injection to be diluted before administration - see below*

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COMPATIBILITY

COMPATIBILITY	
Solution compatibility	sodium chloride 0.45%, sodium chloride 0.9%, glucose 5%, glucose 10%
Solution incompatibility	No information
IV Line compatibility	Aciclovir, caffeine citrate,calcium gluconate,dopamine,fluconazole, furosemide,meropenem,metronidazole,milrinone,potassium chloride sodium bicarbonate,vancomycin,vecuronium
IV Line incompatibility	adrenaline,cefotaxime,dobutamine,esmolol,
	midazolam,noradrenaline,phenytoin,pyridoxine

THIS LIST IS NOT EXHAUSTIVE PLEASE CONTACT PHARMACY FOR FURTHER INFORMATION ON COMPATIBILITY WITH ANY MEDICINES NOT INCLUDED

CAUTIONS, CONTRA-INDICATIONS AND SIDE EFFECTS

- See Summary of Product Characteristics and most recent edition of BNF for Children (links below)

FURTHER INFORMATION

Blood Levels-

- Approximate time to steady state is 10-14 days.
- Therapeutic range 15 to 40mg/Litre.
- Take trough sample, immediately prior to next dose.
- · High extravasation risk.
- Phenobarbital reduces blood levels of Carbamazepine. The effect of Phenobarbital on Phenytoin levels is unpredictable therefore blood levels should be checked if this drug combination is initiated.
- As a general CNS depressant, Phenobarbital may produce respiratory depression requiring assisted ventilation.
- Contains propylene glycol 90%

PH 10 - 11

LICENSED STATUS Not licensed by IV route in children, nor for neonatal abstinence

syndrome.

LINKS BNF for Children: / Electronic Medicines Compendium

APPLICABLE POLICIES West of Scotland Neonatal Guidelines:

Consult local policy if applicable

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Date prepared	May 2016	Date updated	<u>June 2023</u>
Updated by	Maria Tracey	Review Date	June 2026

Administer reconstituted solutions immediately.

All vials, ampoules and infusion bags are for single use only unless otherwise stated.

Dose may vary depending on indication, age, renal function, hepatic function, and concomitant medications. This monograph should be used in conjunction with the package insert, BNF for Children, and Summary of Product Characteristics. For further advice contact your clinical pharmacist or pharmacy department.

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