Paracetamol for PDA Treatment

Neonatal

FORM Ampoule containing 100mg in 10ml

INDICATION Treatment of a haemodynamically significant patent ductus arteriosus in preterm newborn infants

DOSE RANGE

AGE	DOSE	FREQUENCY	ROUTE
All ages	20mg/kg	LOADING DOSE – ONCE only	IV Infusion
23 0/7 to 25 6/7 and ≤ 7 days at time of treatment	12.5mg/kg	Every 6 hours	IV infusion
23 0/7 to 25 6/7 and > 7 days at time of treatment	15mg/kg	Every 6 hours	IV infusion
≥ 26 0/7	15mg/kg	Every 6 hours	IV infusion

- **Maintenance dose to commence SIX hours after loading dose**
- **Check Paracetamol trough level, immediately before THIRD maintenance dose**
- **.Desired level 15 – 25mg/L**
- **FIVE day course**

RECONSTITUTION Already in solution

DILUTION Can be administered undiluted.

Dosage guide
- 10mg in 1ml

METHOD OF ADMINISTRATION By Intravenous Infusion over 15 minutes

COMPATIBILITY

Solution compatibility	Sodium Chloride 0.9%, Glucose 5%
Solution incompatibility	All other IV fluids
IV Line compatibility	Morphine, Midazolam, Vancomycin, Parenteral Nutrition including Lipid
IV Line incompatibility	All other drugs

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

CAUTIONS, CONTRA-INDICATIONS AND SIDE EFFECTS

Caution in hepatic impairment – monitor hepatic function

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

PARACETAMOL initial dosage adjustment

23 0/7 to 25 6/7 weeks gestational age at birth and ≤7 days *at the time of treatment*:

LEVEL	ACTION
< 15mg/L	Increase the dose - 15 mg/kg every 6 hours
15 – 25mg/L	No change – 12.5mg/kg every 6 hours
26 – 34mg/L	Decrease dose - 10mg/kg every 6 hours
35 – 40mg/L	Decrease dose – 10mg/kg every 8 hours
> 40mg/L	Discontinue drug

If the maintenance dose has been increased to 15 mg/kg every 6 hours, check a paracetamol trough level, just before the third maintenance dose – desired level = 15-25 mg/L:

LEVEL	ACTION
< 25mg/L	Continue dosing as 15 mg/kg every 6 hours
26 - 40mg/L	Decrease dose to 12.5mg/kg every 6 hours
> 40mg/L	Discontinue drug

Whenever there has been a change in dose, check a paracetamol trough level, just before the third new maintenance dose – desired level = 15-25 mg/L

23 0/7 to 25 6/7 weeks gestational age at birth and >7 days *at the time of treatment*:

LEVEL	ACTION
< 25mg/L	Continue dosing as 15 mg/kg every 6 hours
26 – 34mg/L	Decrease dose to 12.5mg/kg every 6 hours
35 – 40mg/L	Decrease dose to 10mg/kg every 6 hours
> 40mg/L	Discontinue drug

Whenever there has been a change in dose, check a paracetamol trough level, just before the third new maintenance dose – desired level = 15-25 mg/L

≥26 0/7 weeks gestational age *at birth*:

LEVEL	ACTION
< 25mg/L	No change – 15mg/kg every 6 hours
26 – 34mg/L	Decrease dose to 12.5mg/kg every 6 hours
35 – 40mg/L	Decrease dose to 10mg/kg every 6 hours
> 40mg/L	Discontinue drug

Whenever there has been a change in dose, check a paracetamol trough level, just before the third new maintenance dose – desired level = 15-25 mg/L

Further dosage adjustments

LEVEL	ACTION
< 25mg/L	No change – continue current dosage
26 – 34mg/L	Decrease dose by 20%
35 – 40mg/L	Decrease dose by 30%
> 40mg/L	Discontinue drug

FURTHER INFORMATION

- Do not give with any other preparation containing paracetamol
- Doses higher than the recommended entail the risk of very serious liver damage. Clinical signs and symptoms of liver damage are not usually seen until 2-6 days after administration.
- The solution is clear and slightly yellowish. Discoloured solutions or solutions containing particulate matter should be discarded

PH 5.5

LICENSED STATUS Unlicensed indication

LINKS BNF for Children: / Electronic Medicines Compendium

APPLICABLE POLICIES West of Scotland Neonatal Guidelines:

Consult local policy if applicable

Document Number:	004	Supersedes:	003
Prepared by:	WoS NeoPharm	Checked by	Peter Mulholland
Date prepared	May 2016	Date updated	January 2023
Updated by	Peter Mulholland	Review Date	January 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.