

Paracetamol for PDA treatment

FORM Oral suspension containing 120mg in 5ml

INDICATION Treatment of a haemodynamically significant patent ductus arteriosus in preterm newborn infants less than 36 weeks corrected gestational age at time of treatment.

DOSE RANGE

AGE	DOSE	FREQUENCY	ROUTE
All ages	Loading Dose 15mg/kg	Every 6 hours for 4 doses	Oral
	Maintenance Dose 15mg/kg	Every 12 hours	Oral

Maintenance dose to commence SIX hours after 4th loading dose given

Check Paracetamol level, 4 hours AFTER Second MAINTENANCE dose.

FIVE day course equivalent to TOLERATE trial regimen

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)

Initial DOSAGE ADJUSTMENT

LEVEL (12 hourly dosing)	ACTION
< 19mg/L	Increase the dose and frequency to 15 mg/kg every 6 hours
19 – 25mg/L	No change – 15mg/kg every 12 hours
26 – 35mg/L	Decrease dose– 12.5mg/kg every 12 hours
36 – 40mg/L	Decrease dose – 10mg/kg every 12 hours
> 40mg/L	Discontinue drug

If the maintenance dose has been increased to 15 mg/kg every 6 hours, check a paracetamol level 4 hours AFTER Second MAINTENANCE dose

LEVEL (6 hourly dosing)	ACTION
< 26mg/L	No change – 15mg/kg every 6 hours
26 – 35mg/L	Decrease frequency – 15mg/kg every 8 hours
36 – 40mg/L	Decrease frequency – 15mg/kg every 12 hours
> 40mg/L	Discontinue drug

Further dosage adjustments

LEVEL	ACTION
< 26mg/L	No change – continue current dosage
26 – 35mg/L	Decrease dose by 20%
36 – 40mg/L	Decrease dose by 30%
> 40mg/L	Discontinue drug

FURTHER INFORMATION

- Do not give with any other preparations containing paracetamol. Check before giving dose that no paracetamol has been given for other indications since last PDA dose
- Doses higher than the recommended entail the risk of very serious liver damage. Clinical signs and symptoms of liver

West of Scotland ORAL/ OTHER ROUTE Drug Monographs

damage are not usually seen until 2-6 days after administration.

LICENSED STATUS

Unlicensed use.

LINKS

[BNF for Children:](#) / [Electronic Medicines Compendium](#)

APPLICABLE POLICIES

[West of Scotland Neonatal Guidelines:](#)

Consult local policy if applicable

Document Number:	002	Supersedes:	001
Prepared by:	Peter Mulholland	Checked by	WoS Neonatal Pharmacists
Date prepared	January 2017	Date updated	October 2021
Updated by	Peter Mulholland	Review Date	October 2024

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.