Paracetamol for neonates

BRIEF ADMINISTRATION GUIDE

For detailed information refer to Australasian Neonatal Medicines Formulary paracetamol guideline

1. Medicine

1.1. Indications

- Relief of mild to moderate pain
- Reduction of fever
- Closure of patent ductus arteriosus (PDA)

1.2. Route and Presentation

Intravenous, oral, rectal

(rectal route for pain or fever only, and least preferred route due to variable bioavailability)

- Injection supplied as Paracetamol 500 mg/50 mL (10 mg/mL) vial
- Oral supplied as Paracetamol 250 mg/5 mL (50mg/mL) oral liquid
- Rectal supplied as Paracetamol 50 mg suppository
 - pH of paracetamol 4.5 6.5

1.3. Dose

Analgesia / Antipyretic

Current Weight	Current Weight Loading Dose		Dose interval	
< 2 kg	15 mg/kg	7.5 mg/kg	6 hourly	
2 – 3 kg	15 mg/kg	10 mg/kg	6 hourly	
> 3 kg	20 mg/kg	10 mg/kg	6 hourly	

Note: MenB (Bexsero) vaccination requires 3 doses of prophylactic paracetamol at 15mg/kg/dose. First dose ideally up to 30 minutes prior to vaccination, or at the time of vaccination. Next two doses 6 hours apart.

Patent Ductus Arteriosus

Criteria	Loading Dose	Maintenance Dose	Dose interval
≥28 weeks CGA/PMA and ≥1 kg*	15 mg/kg	15 mg/kg	6 hourly
<28 weeks CGA/PMA and/or <1 kg*	15 mg/kg	7.5 mg/kg **	6 hourly

*Current/best weight

**Higher maintenance doses (15 mg/kg) in extreme preterm infants have been used but there are limited safety data.

Usual treatment duration is 3 days (12 doses) but may be extended if the PDA remains patent on repeat assessment for a further 4 days (maximum 28 doses total).

Notes: Maximum of 4 doses each day

Rectal dosing: DO NOT cut suppositories. Round doses to the nearest suppository strength if this remains a safe dose. If this is not practicable, the oral suspension can be used rectally or use an alternative route of administration.

2. Preparation and Administration

2.1. Compatible fluids

Sodium chloride 0.9%, glucose 5%

2.2. Administration Method

Intermittent IV Infusion

- Draw up the prescribed dose of undiluted solution
- Administer by intravenous infusion over 15 minutes via a Guardrails profiled syringe driver, followed by a flush at the same rate as the paracetamol administered.

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<u>Oral</u>

• Shake the bottle well before measuring the dose.

Draw up the prescribed dose in an oral syringe and administer orally with or without feeds

<u>Rectal</u>

- If suppositories are used, these must not be cut to make part doses.
- Remove the wrapper and insert suppository well up into the rectum

If oral suspension is used: shake the bottle well then draw up prescribed dose in a syringe and administer into the rectum with aid of a feeding tube.

2.3. Monitoring

- Serum creatinine and liver function tests (at least every 48 hours)
- Monitor for injection site reactions before and during infusion
- Observe for signs of hypersensitivity or adverse reactions

2.4. Storage and Stability

- Diluted injection solution must be used within 1 hour of preparation including the infusion time
- Discard any remaining solution in the vial
- Store oral suspension at room temperature (below 25°C)

2.5. Competency for Administration

This procedure is carried out by, or under, the direct supervision of a registered nurse/registered midwife who holds current Te Whatu Ora Waikato Generic Medicine Management and IV certification plus Guardrails competency (if administering IV) as well as Neonatal specific competency NCV/NAC (if administering via CVAD)

2.6. Guardrails

Paracetamol is Guardrail profiled on the CC pump for NICU. Following are the guardrail limits:

Guardrails Drug Name	Paracetamol (load)*	Paracetamol (maint)*		
Concentration (mg/mL)				
Minimum	10	10		
Maximum	10	10		
Dose rate (mg/kg/h)				
Default	60	30		
Soft minimum	58	29		
Soft maximum	80	60		
Hard max	81	61		

3. Associated Documents

- Management of the Haemodynamically Significant Patient Ductus Arteriosis, Waikato NICU guideline #6488
- Immunisations in Neonates and Infants, Waikato NICU guideline #2755

4. References

- Australian Neonatal Medicines Formulary. Paracetamol Drug Guideline. 2022. Available from: <u>www.anmfonline.org/wp-content/uploads/2022/02/Paracetamol -ANMFv4.0 20220203.pdf</u>
- New Zealand Formulary for Children (NZFC) v137. Paracetamol. Available from: https://nzfchildren.org.nz/nzfc 2439
- Truven Health Analytics Inc. Neofax[®] Acetaminophen monograph. Accessed 28th February 2022. Available from: <u>http://www.micromedexsolutions.com.</u>
- Phelps SJ, Hagemann TM, Lee KR, Thompson AJ. The Teddy Bear Book: Pediatric Injectable Drugs. 10th edition. American Society of Health-System Pharmacists; 2013.
- The Royal Children's Hospital Melbourne. Paediatric Injectable Guidelines. Accessed 28th February 2022. Available from: https://pig.rch.org.au.

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- Auckland DHB Newborn Services. Paracetamol (Intravenous) Drug Protocol. February 2011. Available from: <u>https://starship.org.nz/guidelines/paracetamol-intravenous/</u>
- Canterbury DHB Neonatal Services. Paracetamol Drug Information Sheet. October 2012. Available from: <u>http://www.cdhb.health.nz/Hospitals-Services/Health-Professionals/Neonatal-Clinical-Resources/Neonatal-Drug-Information-Sheets</u>.
- New Zealand Hospital Pharmacists Assoc. Inc. Notes on Injectable Drugs 8th ed. Accessed from https://www.noids.nz/wp-content/uploads/2020/11/Paracetamol-S.pdf
- Ainsworth SB. Neonatal Formulary: Drug Use in Pregnancy and the First Year of Life 8th ed. Sean Ainsworth; 2020. Accessed via <u>https://oxfordmedicine.com/view/10.1093/med/9780198840787.001.0001/med-9780198840787-chapter-28</u>
- South Australian Neonatal Medicines Guidelines Workgroup. Paracetamol Clinical Guideline. 11 August 2017.
- Immunisation Handbook 2020, section 13.5 Recommended immunisation schedule. Accessed online via https://www.health.govt.nz/our-work/immunisation-handbook-2020/13-meningococcal-disease#12-5-1

Document Ownership					
Document Authorisor: Natasha Sanders Chair Medicines & Therapeutics Committee					
Document Authorisor: Jutta van den Boom Clinical Director Neonatal Intensive Care Unit					
Document Facilitator: Kerrie Knox Pharmacist					
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