NEONATAL Medication Monograph

PARACETAMOL

This document should be read in conjunction with this **DISCLAIMER**

Oral: Unrestricted: Any prescriber may initiate treatment

IV: Restricted: Requires Neonatologist or relevant specialist review within 24 hours of initiation

⚠ **Check Route of Administration, Dose and Indication**
Caution in Neonates at risk of hepatotoxicity

Presentation	**Oral Mixture:** 250mg/5mL **IV:** 1g/100mL = 10mg/mL
Description	Non-narcotic analgesic and antipyretic
Indications	• **Analgesia:** For relief of postoperative pain and reduce the use of narcotic analgesics in infants ≥ 28 weeks. • **Symptomatic fever** • **Haemodynamically significant Patent Ductus Arteriosis (PDA):** Where indomethacin is contraindicated or 2 courses have failed
Contraindications	Contraindicated where patient has hypersensitivity to paracetamol, severe hepatocellular insufficiency or hepatic failure
Precautions	Risk of haemolysis in patients with G6PD Deficiency with high doses
Dosage	See Page 2
Adverse Reactions	**Common:** nausea, vomiting, constipation, dizziness, pain at injection site, pruritis, hypothermia
	Serious: skin rash/urticarial, thromobocytopaemia, anaphylactic shock, hepatotoxic with chronic use
Compatible Fluids	Glucose 5%, Sodium Chloride 0.9%

<table>
<tr><td>Preparation</td><td>IV: Use undiluted
Oral: Nil</td></tr>
<tr><td>Dosage</td><td>
<u>Analgesia/Antypyretic</u>
<u>Note: IV and Oral</u>
When used for analgesia, an initial loading dose of 20mg/kg/dose may be administered if clinically necessary with the maximum daily dose adhered to as stated below. Give maintenance dose 6 hours post loading dose.
<table>
<tr><th colspan="4">Intravenous Administration</th></tr>
<tr><th>CGA</th><th>Dose</th><th>Frequency</th><th>Max DAILY Dose</th></tr>
<tr><td>≥ 32 weeks</td><td>10mg/ kg/ dose</td><td>Every 6 hours
as necessary</td><td>50mg/ kg/ day</td></tr>
<tr><th colspan="4">Oral Administration</th></tr>
<tr><th>CGA</th><th>Dose</th><th>Frequency</th><th>Max DAILY Dose</th></tr>
<tr><td>28 to 32 weeks</td><td>10mg/ kg/ dose</td><td>Every 6 hours
as necessary</td><td>40mg/ kg/ day</td></tr>
<tr><td>≥ 33 weeks</td><td>15mg/ kg/ dose</td><td>Every 6 hours
as necessary</td><td>60mg/ kg/ day</td></tr>
</table>
<u>Hemodynamically Significant Patent Ductus Arteriosus (PDA)</u>
Oral/IV:
15mg/kg/dose every 6 hours for 5 days.
DA to be reviewed 3 days after course completion
</td></tr>
<tr><td rowspan="2">Adverse Reactions</td><td>Common: nausea, vomiting, constipation, dizziness, pain at injection site, pruritis, hypothermia</td></tr>
<tr><td>Serious: skin rash/urticarial, thromobocytopaemia, anaphylactic shock, hepatotoxic with chronic use</td></tr>
<tr><td>Compatible Fluids</td><td>Glucose 5%, Sodium Chloride 0.9%</td></tr>
<tr><td>Preparation</td><td>IV: Use undiluted
Oral: Nil</td></tr>
<tr><td>Administration</td><td>IV: Infuse over 15 minutes
Oral: Can be given any time with regards to feeds</td></tr>
</table>

Monitoring	Monitor for analgesic response Monitor temperature if used for fever
Interactions	Barbiturates, carbamazepine and phenytoin may increase clearance of paracetamol.
Storage	Store at room temperature, below 25°C
Notes	Measure the paracetamol level if toxicity is suspected, routine monitoring not required. Antidote for paracetamol overdose: Acetylcysteine
References	Truven Health Analytics. Paracetamol. In: NeoFax [Internet]. Greenwood Village (CO): Truven Health Analytics; 2019 [cited 2019 Sept 18]. Available from: https://neofax.micromedexsolutions.com/ Society of Hospital Pharmacists of Australia. Paracetamol: Australian Injectable Drugs Handbook [Internet]. [St Leonards, New South Wales]: Health Communication Network; 2018 [cited 2017 Nov 19]. Available from: http://aidh.hcn.com.au Taketomo CK, Hodding JH, Kraus DM. Pediatric and neonatal dosage handbook. Hudson (OH): Lexi Comp; 2010. Terrin, G., et al. (2016). "Paracetamol for the treatment of patent ductus arteriosus in preterm neonates: a systematic review and meta-analysis." Archives of disease in childhood. Fetal and neonatal edition **101**(2): F127-136. Seymour, R. A., et al. (1984). "A comparative study of the effects of aspirin and paracetamol (acetaminophen) on platelet aggregation and bleeding time." Eur J Clin Pharmacol **26**(5): 567-571. 1Acetaminophen: Paediatric Drug Information [Internet] UpToDate [Online Database] Cited 15/11/2019
Related clinical guidelines	Patent Ductus Arteriosis (PDA)
Related policies	WNHS Policy: High Risk Medication List

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