Paracetamol
Newborn use only

2019

<table>
<tr><td>Alert</td><td>Intravenous paracetamol should be considered a high-risk medicine when administered to infants and young children.
Use of paracetamol should always be preceded by a comprehensive risk assessment and reviewed every 24 hours.
Safety data for paracetamol in extreme preterm infants (< 28 weeks) is limited. It should be used with caution, particularly in the treatment of patent ductus arteriosus.</td></tr>
<tr><td>Indication</td><td>Analgesia
Antipyretic
Adjunct to post-operative analgesia
Treatment of patent ductus arteriosus (PDA)</td></tr>
<tr><td>Action</td><td>Centrally acting analgesic and antipyretic with minimal anti-inflammatory properties. The mechanism of action of paracetamol in reducing pain is not completely defined. Potential mechanisms include inhibition of central prostaglandin synthesis and inhibition of the cyclooxygenase (COX) isoenzyme, particularly the COX-2 isoform.</td></tr>
<tr><td>Drug Type</td><td>Non-narcotic analgesic and antipyretic.</td></tr>
<tr><td>Trade Name</td><td>Intravenous: Paracetamol Actavis; Paracetamol ACT; Paracetamol BNM; Paracetamol IV Pfizer; Paracetamol Kabi; Paracetamol-AFT; Paramat
Oral: Dymadon, Febridol, Panadol (Children)</td></tr>
<tr><td>Presentation</td><td>IV: 500 mg/50 ml (10 mg/ml) vial
Oral: 100 mg/mL drops</td></tr>
<tr><td>Dosage/Interval</td><td><u>Analgesia/Antipyretic/Adjunct to post-operative analgesia</u>
Oral/Intravenous/Rectal[1-3]:
<table>
<tr><th>Weight*</th><th>Loading</th><th>Maintenance</th></tr>
<tr><td><2.0 kg</td><td>15 mg/kg</td><td>7.5 mg/kg every 6 hours</td></tr>
<tr><td>2.0 – 3.0 kg</td><td>15 mg/kg</td><td>10 mg/kg every 6 hours</td></tr>
<tr><td>>3.0 kg</td><td>20 mg/kg</td><td>10 mg/kg every 6 hours</td></tr>
</table>
*Current/best weight

<u>Patent Ductus Arteriosus (treatment course 3-7 days with 48-hourly monitoring of liver function)</u>
Oral/Intravenous[5-9]:
<table>
<tr><th>Criteria</th><th>Loading</th><th>Maintenance</th></tr>
<tr><td>≥28 weeks CGA/PMA and ≥1000 g*</td><td>15 mg/kg</td><td>15 mg/kg every 6 hours</td></tr>
<tr><td><28 weeks and/or <1000 g*</td><td>15 mg/kg</td><td>7.5 mg/kg every 6 hours**</td></tr>
</table>
*Current/best weight
**Higher maintenance doses (15 mg/kg) in extremely premature infants have been used but there is limited safety data.</td></tr>
<tr><td>Maximum daily dose</td><td>60 mg/kg/day</td></tr>
<tr><td>Route</td><td>IV, oral, rectal</td></tr>
<tr><td>Preparation/Dilution</td><td>Intravenous: Use undiluted. Can be diluted to 2 mg/ml for use in ELBW infants using sodium chloride 0.9% or glucose 5%. If diluted, the solution should be used immediately.</td></tr>
<tr><td>Administration</td><td>Intravenous:
Administer over 15 minutes via syringe driver.
Oral:
Can be given with or without feeds. Shake bottle well before measuring dose.
Rectal:
Dilute oral mixture 1:1 with water for rectal doses. Low dose suppositories are not commercially available but can be prepared by selected pharmacy departments. Do not cut suppositories to make part rectal dose.</td></tr>
<tr><td>Monitoring</td><td>Monitor hepatic and renal function.
If signs of acute liver injury (example, raised ALT >50 IU/L) – refer to acetylcysteine formulary and contact Poisons Information Centre (13 11 26 for New South Wales) or local toxicology service.</td></tr>
<tr><td>Contraindications</td><td>Hypersensitivity to paracetamol, active liver disease.</td></tr>
<tr><td>Precautions</td><td>Hepatic impairment, renal impairment, sepsis, dehydration</td></tr>
</table>

Drug Interactions	Paracetamol absorption is increased by substances that increase gastric emptying. Paracetamol absorption is decreased by substances that decrease gastric emptying. Paracetamol may increase chloramphenicol concentrations. The risk of paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic drugs or drugs that induce liver microsomal enzymes such as anticonvulsant agents.
Adverse Reactions	Vomiting, fever, rash, neutropenia, leucopoenia, thrombocytopenia. May cause liver toxicity at high plasma concentrations.
Compatibility	Sodium chloride 0.9%, glucose 5%
Incompatibility	Do not mix with any other intravenous fluids or medications.
Stability	Vials should be used immediately after opening. Any unused solution should be discarded. After dilution in 0.9% sodium chloride or 5% glucose do not store for more than 1 hour (infusion time included).
Storage	IV: Do not store above 30°C. Do not refrigerate or freeze. Oral: Store below 25°C.
Special Comments	Preterm infants may be at increased risk of paracetamol toxicity. Review indications if IV paracetamol is needed for more than 48 hours. Antidote of choice for overdose is acetylcysteine IV infusion. Rectal bioavailability is variable depending on the formulation used. Oral or intravenous routes are preferred.
Evidence summary	Refer to full version.
References	Refer to full version.

Original version Date: 12/12/2016	**Author: ANMF Consensus Group**
Current Version number: 1.4	**Current Version Date: 30/08/2019**
Risk Rating: Low	**Due for Review:** 30/08/2024

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