MONOGRAPH

PARACETAMOL

Scope (Staff):	Medical, Pharmacy, Nursing, Anaesthetic Technicians
Scope (Area):	All Clinical Areas

Child Safe Organisation Statement of Commitment

CAHS commits to being a child safe organisation by applying the National Principles for Child Safe Organisations. This is a commitment to a strong culture supported by robust policies and procedures to reduce the likelihood of harm to children and young people.

This document should be read in conjunction with this DISCLAIMER

DRUG CLASS

Non-opioid analgesic.[1]

INDICATIONS AND RESTRICTIONS

- Mild pain.[1-3]
- Moderate-to-severe pain in combination with other analgesics (e.g. opioids, nonsteroidal anti-inflammatories).[2]
- Symptomatic fever[1-3]
  - There is no clinically significant benefit from combining or alternating paracetamol with ibuprofen to treat fever.[1]
  - There is no evidence that paracetamol prevents febrile seizures. Children with low grade fever may not need paracetamol as fluid and comfort are often sufficient.[1, 3]
  - Prophylactic use of paracetamol to reduce fever and discomfort associated with vaccination is not recommended[3] unless the child is < 2 years old and receiving a meningococcal B vaccine.[4]
- Enteral paracetamol should be used in preference to intravenous paracetamol whenever possible. Switch from IV to oral paracetamol as soon as clinically appropriate.[5]

- Patients who are fasting pre-operatively may still be given oral paracetamol, at least 60 minutes before the operation, unless otherwise directed by the anaesthetist.[6, 7]

CONTRAINDICATIONS

- Hypersensitivity to paracetamol or any component of the formulation.

PRECAUTIONS

- Severe hepatic impairment or pre-existing liver disease: consider dose adjustment due to increased risk of liver toxicity.[1, 3]
    - Cases of hepatic toxicities have been reported in daily doses of < 4000 mg.[3]
- Severe renal impairment or renal failure: consider dose adjustment.[2]
- G6PD deficiency: may increase the risk of haemolysis.[2, 3]
- Immunosuppression, neutropenia or bone marrow suppression: may mask fever as a sign of infection.[2]
- Chronic malnutrition: increased risk of liver injury.[2]
- Severe hypovolemia (e.g. due to dehydration): use IV preparation with caution.[2, 3]

All sources of paracetamol should be taken into account when calculating a patient's total daily dose (e.g. paracetamol-containing combination products).

For oncology patients, always discuss the use of paracetamol with the Oncology team prior to prescribing.

FORMULATIONS

Listed below are products available at PCH, other formulations may be available, check with pharmacy if required:

- Oral suspension – 250 mg / 5 mL
- Suppositories – 125 mg, 250 mg, 500 mg
- IV infusion – 1 g / 100 mL
- Tablets – 500 mg

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Neonates: Refer to Neonatal Medication Protocols

Dosing in Overweight and Obese Children: *Dose based on ideal body weight.*[8]

Intravenous (4 weeks – 18 years)

- 15 mg/kg (up to 1000 mg) every 6 hours; maximum of 60 mg/kg (up to 4000 mg) per day.[8]

Higher than recommended doses can cause liver damage.[2, 5] Ensure no other forms of paracetamol are prescribed and that the maximum total dose of paracetamol is not exceeded.[5]

Oral – immediate release (4 weeks – 18 years)

- 15 mg/kg (up to 1000 mg) every 4 – 6 hours; maximum of 60 mg/kg (up to 4000 mg) per day.[8]
- *Severe pain (inpatient setting):* Maximum daily dose may be increased to 90 mg/kg (up to 4000 mg) per day for a maximum of 48 hours.[1, 8]

Rectal (4 weeks – 18 years)

- 15 – 20 mg/kg (up to 1000 mg) every 6 hours; maximum of 60 mg/kg (up to 4000 mg) per day.[8]

A loading dose of up to 30 mg/kg orally or 40mg/kg rectally (maximum 1000mg) may be used; this must be included in the maximum daily dose.[1, 9]

For chronic dosing (regular paracetamol >1 week), consider using the lowest effective daily dose.[8]

Renal impairment:

eGFR calculator

- CrCl > 30 mL / minute: No dosage adjustment required.[3]
- CrCl ≤ 30 mL / minute: Use with caution; consider decreasing daily dose and extending dosing interval.[3]
- CrCl < 10 mL / minute: Use with caution; administer every 8 hours.[2]
- Intermittent haemodialysis or peritoneal dialysis: Administer every 8 hours.[2]

Hepatic impairment:

- Use the lowest effective dose for the shortest duration as necessary.[2]
- Monitor liver function.

ADMINISTRATION

Intravenous infusion

Caution: IV dose (mg) and volume (mL) mix-ups have caused 10-fold overdoses in young children.[5]

- Use undiluted, or dilute to 1 mg/mL with a compatible fluid and infuse over 15 minutes.[5, 10]
- If diluting: Complete the infusion within one hour of diluting.[5, 10]
- For part-vial or part-bag doses: draw up dose in a suitably sized syringe (do not hang vial or bag).[5, 10]

IM, subcut and IV injections are not recommended.[5, 10]

Oral

- Can be given with or without food.[2]

- Suspension must be shaken thoroughly prior to measuring a dose.[2, 3]

Rectal

- Round to the nearest suppository strength. Do not exceed usual recommended paracetamol total daily dosing.[1]
- Remove wrapper carefully and moisten the suppository with water prior to insertion. Lay the patient on their side and insert the suppository (pointed end first) high into the rectum with a gloved finger.[2]
- Buttocks may be held close together gently to prevent immediate expulsion of the suppository.[2]

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

Compatible fluids:

- Sodium chloride 0.9%, glucose 5%, glucose 10%, Hartmann's.[5, 10]

Compatible at Y-site:

- Plasma-Lyte 148.[5]

Only commonly used drugs are listed below. This is not a complete list of incompatible drugs. Compatibilities of IV drugs must be checked when two or more drugs are given concurrently.

INCOMPATIBLE drugs:

- Aciclovir, metronidazole, chlorpromazine.[2, 5]

MONITORING

- Analgesic response – pain score.
- Body temperature when used as antipyretic.
- Liver function test for patients on long-term paracetamol or with elevated liver enzymes.[2, 3]
- Serum creatinine with long-term use or acute toxicity.[2]
- Serum paracetamol levels in acute overdose or with long-term use in patients with hepatic impairment.[3]

ADVERSE EFFECTS

Common: Increased aminotransferases.[1]

Rare: Malaise, anaphylaxis, skin reactions (including Stevens-Johnson syndrome, toxic epidermal necrolysis and exanthematous pustulosis), blood disorders (including neutropenia, thrombocytopenia, leukopenia and pancytopenia), liver damage.[1, 2, 9]

Rebound headache can occur with chronic use.[2]

Intravenous infusion can cause hypertension, hypotension, flushing, tachycardia, muscle cramps, agitation, headache, nausea, vomiting or constipation.[2, 3]

STORAGE

- Store below 25 ºC.[11-14]
- IV infusion (*Paracetamol BNM*®) and oral suspension (*Dymadon*®): Protect from light.[12, 14]

INTERACTIONS

This medication may interact with other medications; consult PCH approved references (e.g. Clinical Pharmacology), a clinical pharmacist or PCH Medicines Information Service on extension 63546 for more information.

Please note: The information contained in this guideline is to assist with the preparation and administration of **paracetamol**. Any variations to the doses recommended should be clarified with the prescriber prior to administration

Related CAHS internal policies, procedures and guidelines

Analgesia (health.wa.gov.au)

Post-operative: Analgesia (health.wa.gov.au)

Tonsillectomy and Adeno-tonsillectomy Post-operative Management (health.wa.gov.au)

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Useful resources (including related forms)

Pain Management - Health Facts

This document can be made available in alternative formats on request for a person with a disability.

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