High-Risk Medicine Standard: Paracetamol
PRINTABLE STANDARD

Last updated: 26 February 2024. **Printed copies are uncontrolled and should not be relied upon as up to date.**

Paracetamol is an effective analgesic and antipyretic that is well tolerated. In both adults and children, paracetamol is indicated as first line therapy for mild to moderate pain and symptoms of fever. Paracetamol may be considered a high-risk medicine for certain population groups at risk of hepatotoxicity.

Adverse events associated with paracetamol toxicity have been associated with:

- concomitant administration of intravenous paracetamol and oral paracetamol
- accidental overdose due to concurrent administration of regular and when required (PRN) paracetamol
- accidental overdose due to lack of dose adjustments in underweight patients
- use of multiple paracetamol-containing products concurrently.

This standard outlines the minimum actions required to mitigate risks associated with paracetamol use. This standard does not contain clinical guidance on paracetamol medicine use.

Minimum requirements for clinical protocols

The Drug and Therapeutics Committee must approve any clinical protocols relating to paracetamol and ensure inclusion of the following, at a minimum:

- any specific training, qualifications, skills or competencies required to prescribe or administer paracetamol
- requirements for patient and/or carer education (see *Patient information/education* section).

Governance requirements

Adherence to the requirements specified in this standard is to be monitored by governance committees (for example, Drug and Therapeutics Committee) and service managers (including, but not limited to, Directors of Pharmacy and Nurse Unit Managers). An implementation checklist is available and can be used by facilities and individual units to determine compliance with these requirements.

Prescribing

- Dose adjustments are to be considered when prescribing paracetamol for:
  - underweight patients
  - oedematous patients and those above a healthy weight
  - frail and/or older persons
  - patients with existing clinical conditions (such as renal or hepatic impairment)
  - any other factors that may affect drug metabolism and excretion.
- Paracetamol (and/or paracetamol combination products) are only to be ordered as a regular medication or as required 'PRN' medication, not both. Ordering in both the regular and as required 'PRN' sections of the chart may potentially lead to overdose. Orders are to be expressed in milligrams (mg) or grams (g) per dose.
- Orders are only to specify a single route (oral, rectal or intravenous).
- The maximum duration of therapy is to be documented for all intravenous orders.
- Orders for oral paracetamol are to be reviewed regularly and ongoing analgesic requirements assessed.
- Orders for intravenous paracetamol are to be reviewed every 24 hours with a switch to oral paracetamol therapy or cessation as soon as clinically appropriate.
- For paper-based prescribing, all orders for paracetamol (and/or paracetamol combination products) are to include the active ingredient name.
- Prior to prescribing, clinicians are to ascertain if paracetamol has been recently ingested, check that no other formulations of paracetamol are concurrently prescribed or recently administered, ensure the time interval between doses is appropriate and that the administration of the order will not result in the patient exceeding the safe maximum daily dose of paracetamol (from all sources including combinations containing paracetamol).

Administration

- Prior to administering paracetamol (including nurse/midwife-initiated paracetamol), clinicians are to ascertain if paracetamol has been recently ingested (by checking with the patient and the medication chart), check that no other formulations of paracetamol are concurrently prescribed or recently administered, and that the administration of the dose will not exceed the safe maximum daily dose of paracetamol (from all sources including combination paracetamol / codeine combinations).
- In circumstances where the dose is calculated based on patient weight, for example, paediatric patients, the dose is not to exceed the maximum recommended paracetamol dose.

- An independent second person check is to be employed when administering intravenous paracetamol and all doses administered to paediatric patients (irrespective of the route of administration) unless there is approval from the local Drug and Therapeutics Committee to administer without a second person check. The second person check processes are outlined in the NSW Health Policy Directive *Medication Handling* (PD2022_032) including circumstances where a second person check is not mandated (for example, when a medicine is administered by an authorised prescriber).

Patient information/education

- Where possible, patients and/or their carers being discharged on paracetamol are to receive confirmation of their current paracetamol regimen at the time of discharge. If patients have been initiated on new paracetamol therapy, the patients and/or their carer are to be provided with specific information and education regarding paracetamol administration where required.
- Discharge supply of paracetamol is to display the maximum dose of paracetamol per 24 hours on the dispensing label.
- Professional Health Care Interpreters are to be utilised for patients and/or carers who are not fluent in English or who have hearing or visual impairments.

References

- Caparrotta, TM., Antoine, DJ. and Dear, JW. Are some people at increased risk of paracetamol-induced liver injury? A critical review of the literature. European Journal of Clinical Pharmacology, 2017; 74(2):147–160.
- NSW Therapeutic Advisory Group. Intravenous Paracetamol Use. Addendum to the 2008 'Paracetamol Use' Position Statement of the NSW Therapeutic Advisory Group. [Internet]. Available from: https://www.nswtag.org.au/wp-content/uploads/2017/07/paracetamol-iv-addendum-dec-2012.pdf. Published December 20, 2012. Accessed November 27, 2023.
- Australian Medicines Handbook. Paracetamol. [Internet]. Available from: https://amhonline.amh.net.au.acs.hcn.com.au/chapters/analgesics/drugs-pain-relief/non-opioid-analgesics/paracetamol. Updated July 2023. Accessed November 27, 2023.