

INTRAVENOUS PARACETAMOL ADMINISTRATION - SCH

DRUG PROTOCOL[®]

DOCUMENT SUMMARY/KEY POINTS

NOTE: This document is to be read in conjunction with [Paracetamol - SCH Practice Guideline](#) for specific advice, SCH approved prescribers, indications, dose and safety issues with IV paracetamol in paediatric patients.

- IV paracetamol is approved for use as an analgesic by authorised prescribers where:
 - Acute pain of mild to moderate severity; **AND**
 - Enteral administration is not possible **AND**
 - Patient is a term neonate or older
- All IV paracetamol orders must be reviewed every 24 hours

CHANGE SUMMARY

- Updated references and additional safety measures in line with Paracetamol – SCH Practice Guideline.
- Additions:
 - Not to be used in patients concurrently taking oral medications
 - May be prescribed by CICU Fellows and Pain team
- Rapid Response to be called if there are signs of an allergic reaction

READ ACKNOWLEDGEMENT

- All SCH clinical staff involved in the administration of Intravenous paracetamol should read and acknowledge this document.

Note: Separate Practice Guidelines may be required to cover all aspects of management.

This document reflects what is currently regarded as safe practice. However, as in any clinical situation, there may be factors which cannot be covered by a single set of guidelines. This document does not replace the need for the application of clinical judgement to each individual presentation.

Approved by:	SCHN Policy, Procedure and Guideline Committee	SCH Medicines Advisory Group
Date Effective:	1 st June 2013	Review Period: Annual
Team Leader:	QUM & Medication Safety Pharmacist	Area/Dept: Pharmacy

Background^{1,2,3}

- To be read in conjunction with [Paracetamol - SCH Practice Guideline](#) for specific advice, SCH approved **prescribers, indications, dose** and **safety issues** with IV paracetamol in paediatric patients.
- IV paracetamol 10mg/mL became available for use in Australia in 2005 and has been used in paediatrics with limited clinical efficacy and safety information. Since this time the manufacturer, Bristol Myers Squibb (BMS) together with the Therapeutic Goods Administration applied additional safety advice for IV paracetamol in children and neonates in response to a number of toxicity reports internationally attributed to concurrent use of oral paracetamol, dose calculation errors, non-adherence to labelling directions and tenfold errors due to confusion between 'mg' and 'mL'. Recommendations by BMS include the use of 7.5mg/kg every 6 hours for patients under 10kg, New South Wales Therapeutics Advisory Group and the Australian Medicines Handbook Children's Dosing Companion endorse the previous recommendations.
- Note: Orders must be reviewed every 24 hours and enteral paracetamol substituted for the IV formulation at the earliest opportunity.

Approved Indications

- **Indications**

Where possible, oral dosing is preferred (including administration of a loading dose for pre-medication)

- i. IV paracetamol is approved for use as an analgesic **IF**:
 - acute pain of mild to moderate severity; **AND**
 - enteral administration is not possible, e.g. Nil By Mouth(NBM) peri-operatively for surgical reasons (e.g. acute abdomen, appendicitis, multi-trauma, mucositis-related pain); **AND**
 - patient is a term neonate or older
 - orders are being reviewed every 24hrs
- ii. IV paracetamol is **NOT** approved for use in the following circumstances:
 - preterm neonates
 - If paracetamol was administered in the preceding 6 hours (including any oral or rectal loading dose)
 - Patient is concurrently taking oral medications Risk factors for hepatotoxicity are present (see [Table 1 Paracetamol - SCH Practice Guideline](#))

Presentation²

- Colourless 10mg/mL solution
- 500mg (50mL) vials (Perfalgan[®])
- 1g (100mL) infusion bag

Dose⁶

- **Birth(term) to 1 month:** 10 mg/kg 6 hourly. **Maximum 40 mg/kg/day[§]**
- **1 month and older: 15mg/kg/dose every 6 hours *** (maximum 1g per dose)
 - **Maximum 60mg/kg *[§]** (maximum 4 g per 24 hours)

* **based on ideal body weight** see Drug Dosing for Overweight and Obese Patients-SCH.

§ Maximum daily dose reflects maximum dose each 24 hours

Authorised Prescribers

- Anaesthetists for use in the operating theatres as a single dose only
- Postoperative use after consultation with the SCH anaesthesia and pain departments
- Haematology/Oncology consultants
- Intensive Care consultants and fellows

Administration

- IV paracetamol should not be mixed with other medications.
- The product contains no preservatives and is intended for single use only. Do NOT refrigerate.

Administering accurate dose of IV paracetamol

CAUTION: DO NOT inadvertently inject oral liquid paracetamol in an intravenous line. Liquid medications must be administered with an oral syringe.

Doses under 500mg⁵

1. Use Perfalgan[®] 50mL (500mg) vial
2. Withdraw in a syringe the amount of IV paracetamol prescribed.
3. Discard remaining contents of vial
4. Administer via sideline syringe infusion pump over 15 minutes.

Doses exceeding 500mg⁵

CHECK: If you are administering a dose 500mg or greater your patient must have an ideal body weight above 33 kg.²

1. Calculate the volume of IV paracetamol needed.
e.g. for a 700mg dose, 70mL is required to be infused.
2. Using the 100mL (1gram) infusion bag
3. Withdraw the amount prescribed.
4. Discard the unwanted portion.
5. Infuse either via sideline syringe infusion pump or burette and volumetric pump over 15 minutes.

Safety and Patient Monitoring^{4,5,6}

Minor adverse reactions include:

- Pain or reaction at injection site
- Nausea & vomiting

If any of these reactions occur they should be clearly documented, if they persist the Pain Team should be notified.

Hepatotoxicity is extremely rare with paracetamol administration (IV or oral), but can occur if therapeutic doses are exceeded or the patient has risk factors for hepatotoxicity – see [Paracetamol – SCH Practice Guideline](#).

Signs of allergic reaction:

Shortness of breath, wheezing or difficulty breathing, swelling of the lips, face, tongue or any other parts of the body, rash, itching or hives on the skin.

If any of these happen, stop infusion and call a Rapid Response.

Accidental overdose:

Symptoms of accidental overdose appear within 24 hours and include nausea, vomiting, anorexia, pallor and abdominal pain.²

In the case of accidental IV overdose, established management guidelines have not been validated and standard nomograms are not to be used in their current state. Due to the bioavailability of IV paracetamol signs of toxicity may appear earlier and at lower doses when compared with rectal or oral overdose. Any suspected overdose should be discussed with SEATS – South-East Area Toxicology Service (via switch) as soon as practicable.^{7,8}

- **Additional Intravenous Safety Issues**
 - Clinicians should take special precautions to ensure that oral paracetamol liquid is not administered inadvertently by the IV route (as has been reported to occur with other medications that are available in both forms, with serious consequences for the patient). Oral syringes must be used when administering oral liquids .

Contacts

- For further information contact the Acute Pain Service: (CNCs page: 42563 or 43514 Pain Fellow p 47229
- If an inadvertent overdose is suspected contact SEATS – South-East Area Toxicology Service (via switch).

References

1. Dear Healthcare Professional Letter. Bristol-Myers Squibb Australia Pty Ltd. May, 2012
2. Bristol Myers Squibb, Personal Communication Skinner, J 04 July 2012
3. NSW Therapeutic Advisory Group. Addendum to the 2008 'Paracetamol Use' Position Statement of the NSW Therapeutic Advisory Group Inc. December 2012 [Available at: <http://www.ciap.health.nsw.gov.au/nswtag/reviews/position-statements.html>] Accessed on 29/04/2013
4. Paediatric Formulary Committee. BNF for Children [online]. London: BMJ Group, Pharmaceutical Press, and RCPCH Publications. [Accessed via <http://www.ciap.health.nsw.gov.au/home.html>] Last Updated June 2015 Accessed on 19/6/15]
5. MIMSONline. St Leonards, NSW: UBM Medica; Accessed 16/06/2015
6. *AMH Children's Dosing Companion* [online]. Adelaide: Australian Medicines Handbook Pty Ltd; [Available from: <https://childrens.amh.net.au/>] Last Updated January 2015 Accessed on 19/6/15]
7. Berling I, Anscombe M et al. Intravenous paracetamol toxicity in a malnourished child, *Clinical Toxicology*; 2012; 50; 74-76
8. Dart R, Rumak B. Intravenous acetaminophen in the United States Iatrogenic dosing errors. *Pediatrics* 2012; 129; 349

Copyright notice and disclaimer:

The use of this document outside Sydney Children's Hospitals Network (SCHN), or its reproduction in whole or in part, is subject to acknowledgement that it is the property of SCHN. SCHN has done everything practicable to make this document accurate, up-to-date and in accordance with accepted legislation and standards at the date of publication. SCHN is not responsible for consequences arising from the use of this document outside SCHN. A current version of this document is only available electronically from the Hospitals. If this document is printed, it is only valid to the date of printing.