Ballarat Health Services

Neonatal Drug Guideline

PARACETAMOL (PERFALGAN®)

DESCRIPTION AND INDICATION FOR USE

Intravenous paracetamol is indicated for relief of mild to moderate pain where an intravenous route of administration is considered clinically necessary. Paracetamol is thought to provide analgesia via inhibition of central prostaglandin synthesis and modulation of inhibitory descending serotonergic pathways. Paracetamol has negligible anti-inflammatory effects.

No safety and efficacy data are available for this product for use in premature neonates. Clinical trials examining the pharmacokinetics of Perfalgan® in neonates and infants < 6 months of age are limited, however small studies have shown that in neonates the plasma half-life is longer, AUC is larger and clearance is lesser than in infants.

PRESCRIBING RESTRICTIONS: Consultation with paediatric registrar, fellow or consultant paediatrician required prior to use

DOSE

NB: Dosing is based on patient weight.

IV:	Preterm neonate (< 37 weeks):	7.5 mg/kg/dose 6 - 8 hourly PRN *
	Term neonate (≥ 37 weeks):	10 mg/kg dose 6 hourly PRN *
	Infant and child < 50 kg:	15 mg/kg/dose 6 hourly PRN #

* For neonates, maximum daily dose must NOT exceed 30 mg/kg/24 hours (includes all medicines containing paracetamol and all routes of administration).
# For infants, maximum daily dose must NOT exceed 60 mg/kg/24 hours (includes all medicines containing paracetamol and all routes of administration).

RECONSTITUTION/DILUTION

Vial = 500 mg in 50 mL (10 mg/mL)

Perfalgan® vials should NOT be hung directly for infusion for neonates due to the small volume of the product to be administered.

IV: Withdraw required dose from vial into a 5 mL or 10 mL syringe and administer undiluted

If dilution is required: Perfalgan® solution may be diluted using either a sodium chloride 0.9% or glucose 5% up to a one-tenth dilution (one volume paracetamol injection into nine volumes diluent). The diluted solution must be used within one hour following its preparation (infusion time included).

NOT for IM, subcut administration

Single dose vial – use a new vial for each dose and discard any remaining solution

ROUTE AND METHOD OF ADMINISTRATION

IV: Infuse slowly over 15 minutes via syringe pump

COMPATIBILITY INFORMATION

Please contact your ward pharmacist for information on drugs or fluids not appearing in the table below. Medications that are not routinely used in the Special Care Nursery have not been included in this table and may be incompatible.

	Compatible	Incompatible
Fluids	Glucose 5%*, Sodium chloride 0.9%*	
Drugs		Infuse alone

***** If diluted, the solution should be used immediately. However, if the solution is not used immediately, do not store for more than one hour (infusion time included).

SIDE EFFECTS

- Observed in clinical trails in children with incidence of > 1%:
    - Injection site pain or reaction, nausea, vomiting, abdominal pain
- Rare: hypotension, rash, raised liver transaminases, blood dyscrasias
- Very rare: hypersensitivity reactions, acute renal failure

SPECIAL PRECAUTIONS

- Contraindicated in patients with hepatic failure or hepatocellular insufficiency
- Review ongoing treatment after 48 hours and change to oral administration as soon as practical
- Caution in patients with severe renal impairment, G6PD, poor enteral fed intake, dehydration

DRUG INTERACTIONS

Enzyme inducing agents e.g amoxicillin + clavulanic acid, carbamazepine, phenobarbitone, phenytoin
Co-administration may result in an increased level of hepatotoxic metabolites, use with caution

Phenytoin
Co-administration may result in decreased paracetamol effectiveness and an increased risk of hepatotoxicity. Avoid large and/or chronic doses of paracetamol and monitor for hepatotoxicity

NURSING RESPONSIBILITIES

- Observations/Monitoring:
    - Observe injection site
    - Pain assessment
    - Observe for side effects
    - Liver function tests with prolonged administration
- Do NOT store solution in refrigerator or freezer
- Ensure maximum daily dose is NOT exceeded (30 mg/kg/24 hours - includes all medicines containing paracetamol and all routes of administration)
- The volume of Perfalgan® (10 mg/mL) administered to children ≤ 10 kg should never exceed 7.5 mL per dose – this is a safety check that can be carried out to assist with the prevention of unintentional administration errors.

REFERENCES:

- Allegaert K and Palmer GM et al, *The pharmacokinetics of intravenous paracetamol in neonates: size matters most*, Archives of Disease in Childhood, 2011; 96(6):575-580
- British Medical Association and the Royal Pharmaceutical Society of Great Britain. British National Formulary for Children. UK: BMJ Publishing Group. July 2014.
- NSW Therapeutic Advisory Group. Intravenous Paracetamol Use Addendum. December 2012 Available at: http://www.ciap.health.nsw.gov.au/nswtag/documents/publications/position-statements/paracetamol-iv-addendum-dec-2012.pdf