MONOGRAPH

Cefotaxime Monograph - Paediatric

Scope (Staff):	Medical, Pharmacy, Nursing
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

QUICKLINKS

Dosage/Dosage Adjustments	Administration	Compatibility	Monitoring

DRUG CLASS

Broad spectrum cephalosporin.[1-5]

INDICATIONS AND RESTRICTIONS

- Cefotaxime is active against the majority of enteric Gram-negative bacilli, *Streptococcus pneumoniae* and has dose dependent activity against methicillin susceptible *Staphylococcus aureus* (MSSA). It has good CNS penetration.[4]
- Ceftriaxone is preferred to cefotaxime in all patients except neonates.

IV/IM: Monitored (orange) antibiotic

Cefotaxime is indicated for use as per the indications stipulated in Formulary One. For any other use, phone approval must be obtained from ChAMP before prescribing as per the Children's Antimicrobial Management Program (ChAMP) Policy.

CONTRAINDICATIONS

- Hypersensitivity to cefotaxime, any component of the formulation or patients with a history of high risk allergy to cephalosporins.[2, 3, 5-7]

PRECAUTIONS

- Cefotaxime may be prescribed in selected patients with high risk allergy to another Beta-lactam sub-class (e.g. some penicillins, carbapenems) in discussions with immunology.[3, 5, 7, 8]
- In patients with a previous low risk reaction to cefotaxime or another cephalosporin (delayed rash [>1hr after initial exposure] without mucosal or systemic involvement) the risk of subsequent reaction is low. Re-challenge may be acceptable in discussion with immunology
- Rapid IV injection has resulted in life-threatening cardiac arrhythmias; ensure IV injections are given over a minimum of 3 to 5 minutes.[3, 5-7, 9]
- Each gram of cefotaxime contains 48 mg (2.1 mmol) of sodium.[2, 6, 9]
- High doses of cefotaxime are associated with an increased risk of neutropenia.[3]

FORMULATIONS

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

- 1 gram powder for injection vial

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Neonates: Refer to Neonatal Medication Protocols

IV/IM (Children ≥ 4 weeks):

- **Usual dose:** 50 mg/kg/dose (to a maximum of 2 grams) 8 hourly.[1, 3, 5]
- **Severe infections (e.g. meningitis, orbital cellulitis):** 50 mg/kg/dose (to a maximum of 2 grams) 6 hourly.[1, 3, 4]

Dosing in Overweight and Obese Children: Dose based on measured body weight.[10]

Renal impairment:

eGFR calculator

eGFR	Usual dose[5]	Severe infections[5]
≥ 50 mL/minute/ 1.73m^2	No adjustment required	No adjustment required
≥ 30 to < 50 mL/minute/ 1.73m^2	35 mg/kg/dose every 8 to 12 hours	70 mg/kg/dose every 8 to 12 hours
≥ 10 to < 30 mL/minute/ 1.73m^2	35 mg/kg/dose every 12 hours	70 mg/kg/dose every 12 hours
< 10 mL/minute/ 1.73m^2	35 mg/kg/dose every 24 hours	70 mg/kg/dose every 24 hours

Hepatic impairment:

- No dosage adjustments are required for hepatic impairment. [5, 11]

RECONSTITUTION & ADMINISTRATION

IV Reconstitution:

- Reconstitute each 1 gram vial with the volume of water for injection in the table below. Further dilution with a compatible fluid to a concentration of 40 mg/mL is required prior to IV infusion.[2, 12]

Vial strength	Volume of water for injection required[2, 13]	Resulting concentration
1 gram	9.6 mL (powder volume 0.4 mL)	100 mg/mL
2 gram	9 mL (powder volume 1 mL)	200 mg/mL

IV Administration:

IV injection:

- Dilute to a final concentration of 100 mg/mL or weaker and give by slow IV injection over 3 to 5 minutes.[2, 5, 13]
- **Note:** life threatening arrhythmias have occurred with rapid IV injection (when administered over 1 minute). Ensure IV injections are given over 3 to 5 minutes.[9, 13]

IV infusion:

- Dilute to a final concentration of 40 mg/mL or weaker with compatible fluid and infuse over 15 to 30 minutes.[2, 5, 13]

IM reconstitution:

- Reconstitute each 1 gram vial with the volume of water for injection or lidocaine 0.5% in the table below.
- To obtain a lidocaine 0.5% solution, dilute lidocaine 1% with an equal quantity of water for injection to make a 0.5% solution.[13]
- **NOTE: Preparations with lidocaine 0.5% as diluent must NEVER be given intravenously.**[2, 13]

Vial strength	Volume of water for injection or lidocaine 0.5% required[2, 13]	Resulting concentration
1 gram	2.6 mL (powder volume 0.4 mL)	330 mg/mL
2 gram	5 mL (powder volume 1 mL)	330 mg/mL

IM Administration:

- For doses higher than 1 gram, the dose must be split between 2 sites.[8]
- Administer via deep injection into a large muscle mass.[2, 13]
- Refer to Intramuscular (IM) injections (internal link)

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

Compatible fluids:

- Glucose 5% and 10%
- Sodium chloride 0.9%
- Glucose 5% / Sodium chloride 0.9%
- Glucose 5% / Sodium chloride 0.45%
- Hartmann's.[2, 9, 13]

Compatible at Y-site:

Compatibilities of IV drugs must be checked when two or more drugs are given concurrently.

MONITORING

- Renal, hepatic and haematological function should be monitored weekly with prolonged therapy (i.e. longer than 7 days).[3, 7]

ADVERSE EFFECTS

Common: diarrhoea, nausea, abdominal pain, vomiting, pain and inflammation at injection site, rash, headache, dizziness, allergy, *Clostrioides difficile*-associated disease.[3, 8]

Infrequent: anaphylaxis, angioedema[8]

Rare: life-threatening arrhythmias with rapid IV administration, neurotoxicity (e.g. confusion, seizures, encephalopathy) especially with high doses and/or renal impairment, blood dyscrasias (e.g. neutropenia, eosinophilia, leucopenia), thrombocytopenia, bleeding, renal impairment, immunologic reactions.[3, 7, 8]

STORAGE

- Store vials below 25˚C and protect from light.[2, 6, 9]
- Store syringes prepared by Pharmacy Compounding Service (PCS) between 2 -8˚C and protect from light.[2, 5]

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 **cefotaxime.** Any variations to the doses recommended should be clarified with the prescriber prior to administration

Related CAHS internal policies, procedures and guidelines

Antimicrobial Stewardship Policy

ChAMP Empiric Guidelines and Monographs

KEMH Neonatal Medication Protocols

References

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