<table>
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<th>MONOGRAPH</th>
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<td><strong>Cefotaxime Monograph - Paediatric</strong></td>
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| Scope (Staff): | Medical, Nursing, Pharmacy |
| Scope (Area): | Perth Children’s Hospital (PCH) |

This document should be read in conjunction with this DISCLAIMER

### DESCRIPTION
- Cefotaxime is a 3rd generation broad spectrum cephalosporin, it interferes with bacterial cell wall peptidoglycan synthesis by binding to penicillin-binding proteins resulting in cell lysis.\(^1,2\)\(^\text{[1]}\)

### INDICATIONS AND RESTRICTIONS
- Cefotaxime is active against the majority of community-associated enteric Gram-negative rods, beta-haemolytic Streptococci, *Streptococcus pneumoniae* and methicillin susceptible *Staphylococcus aureus* (MSSA).\(^3,4\)\(^\text{[2]}\)
- Ceftriaxone is preferred to cefotaxime in all patients except neonates.

**IV: Monitored (orange) antibiotic**
- If the use is consistent with a standard approved indication, this must be communicated to ChAMP by documenting that indication on all prescriptions (inpatient and outpatient).
- The ChAMP team will review if ongoing therapy is required and/or if the order does not meet ChAMP Standard Indications.
- If use is not for a standard approved indication, phone approval must be obtained from ChAMP before prescribing.

### CONTRAINDICATIONS
- Cefotaxime is contraindicated in patients with a history of severe allergy to a cephalosporin antibiotic or any component of the formulation.
- Care should also be taken in those with a history of allergy to penicillins and carbapenems as cross reactivity may occur between penicillins, cephalosporins and carbapenems.\(^1,2,5,6\)\(^\text{[3]}\)

### PRECAUTIONS
- Rapid IV injection has resulted in life-threatening cardiac arrhythmias; ensure IV injections are given over a minimum of 3 to 5 minutes.\(^1,2,7\)\(^\text{[4]}\)
- Ensure the required dose reductions are used in renal impairment. There is an increased risk of seizures if high
doses are used in renal impairment.\(^{(6)}\)

| FORMULATIONS | **Available at PCH:**  
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<tr>
<td></td>
<td>• 1 gram powder for injection vial</td>
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| **Other formulations available:** | • 500mg powder for injection vial (multiple generic brands).  
|              | • 2 gram powder for injection vial (multiple generic brands). |

| DOSAGE | • The doses listed below fall within the standard range.  
|        | • Higher doses may be prescribed for certain situations in consultation with an infectious diseases or clinical microbiology consultant.  
|        | **Neonates (<1 month of age):**  
|        | • Please refer to neonatal clinical care drug protocols  
| IV: 1 month to 18 years | • **Usual dose:** 25-50mg/kg/dose (to a maximum of 2gram) 8 hourly.\(^{(1, 9)}\)  
|        | • **Severe infections (e.g. meningitis):** 50mg/kg/dose (to a maximum of 2grams) 6 hourly.\(^{(1, 9)}\) |

| DOSAGE ADJUSTMENT | **Dosage adjustment required in renal impairment:**  
|                  | To calculate the estimated glomerular filtration rate (eGFR) use the formula available via the following link. \(^{(4)}\) This formula should only be used for children older than one year  
|                  | eGFR \(\text{mL/min/}1.73\text{m}^2\) = \(36.5 \times \text{height (in cm)}\) \(\text{ Serum creatinine (micromol/L)}\)  
|                  | • Dosage adjustment may be required in cases of impaired renal function (with creatinine clearance of less than 50 mL/min).  
|                  | • eGFR: 30-50mL/minute: 100% dose given 8 to 12 hourly  
|                  | • eGFR: 10-29 mL/minute: 100% dose given 12 hourly  
|                  | • eGFR: <10mL/minute: 100% dose given 24 hourly.\(^{(2, 8)}\)  
|                  | **Dosage adjustment required in hepatic impairment:**  
|                  | • No dosage adjustments are required for hepatic impairment.  
|                  | • If concomitant renal impairment, use the renal dose adjustments stated above.\(^{(2)}\)  

| RECONSTITUTION | IV:  
|                | • Reconstitute each 1gram vial with 9.6mL of water for injection to give a final concentration of 100mg/mL.\(^{(7)}\) |
- Further dilution may be required for administration (see below for further information).\(^{(7)}\)

### Administration

**IV injection:**
- Dilute to 100mg/mL or weaker and give by slow IV injection over 3 to 5 minutes.\(^{(7)}\)
- **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.\(^{(1, 2, 7)}\)

**IV infusion:**
- Dilute to 40mg/mL or weaker with compatible fluid and infuse over 15 to 30 minutes.\(^{(7)}\)

### Monitoring
- Renal, hepatic and haematological function should be monitored weekly with prolonged therapy (i.e. longer than 7 days).\(^{(1, 2, 6, 10)}\)

### Adverse Effects
- **Common:** diarrhoea, nausea, vomiting, pain and inflammation at injection site, rash, headache, dizziness, allergy, *Clostridium difficile*-associated disease.\(^{(1, 5)}\)
- **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), thrombocytopenia, bleeding, renal impairment, immunologic reactions (including eosinophilia, drug fever, anaphylaxis, angioedema, urticaria, haemolytic anaemia, Stevens-Johnson syndrome, toxic epidermal necrolysis, interstitial nephritis, arthritis, serum sickness-like syndrome).\(^{(1, 5)}\)

### Compatible Fluids
- Glucose 5% and 10%
- Sodium chloride 0.9%
- Glucose/sodium chloride solution
- Hartmann’s.\(^{(7)}\)

### Storage
- Store vials below 25°C and protect from light.\(^{(7)}\)
- Store syringes prepared by Pharmacy Compounding Service (PCS) between 2 and 8°C.
- Reconstituted solutions should be protected from light.
## INTERACTIONS

- Cefotaxime may interact with other medications; please consult PCH approved references (e.g. *Clinical Pharmacology*), your ward pharmacist or Pharmacy on extension 63546 for more information.
  - IV aminoglycoside antibiotics are inactivated by IV penicillins and cephalosporins.
  - Aminoglycoside antibiotics are rapidly bactericidal and should be administered first. The line should then be flushed well with a compatible fluid and the penicillin administered.\(^{(5, 7)}\)
  - Care should be taken and renal function monitored when used with other nephrotoxic drugs (e.g. aminoglycosides or potent diuretics) due to an increased risk of neurotoxicity.\(^{(1)}\)
  - Cefotaxime may affect platelet aggregation and prolong bleeding time. Care should be taken when used in conjunction with other medications that may affect the clotting process.\(^{(5)}\)

## COMMENTS

- Each gram of cefotaxime contains 48mg (2.1mmol) of sodium.\(^{(7)}\)
- Cefotaxime has good CNS penetration and is widely distributed into many body fluids and tissues (including; liver, kidneys, bone, sputum, pleural and synovial fluid).\(^{(2)}\)

## MANUFACTURER SAFETY DATA SHEET (SDS)

To access to the Manufacturer SDS for this product, use the following link to [ChemAlert](http://www.chemalert.com).

**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 internal policies, procedures and guidelines

- **Antimicrobial Stewardship Policy** (Medication Management Manual)
- **ChAMP Empiric Guidelines** (ChAMP Manual)

References

Cefotaxime Monograph - Paediatric

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