**MONOGRAPH**

**Cefotaxime Monograph - Paediatric**

<table>
<thead>
<tr>
<th>Scope (Staff):</th>
<th>Medical, Nursing, Pharmacy</th>
</tr>
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<tbody>
<tr>
<td>Scope (Area):</td>
<td>PCH</td>
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This document should be read in conjunction with this [DISCLAIMER](#).

**DESCRIPTION**

- Cefotaxime is a broad spectrum cephalosporin, it interferes with bacterial cell wall peptidoglycan synthesis by binding to penicillin-binding proteins resulting in cell lysis.\(^{1,2}\)
- Cefotaxime is active against the majority of community-associated enteric Gram-negative rods, beta-haemolytic Streptococci, Streptococcus pneumoniae and methicillin susceptible Staphylococcus aureus (MSSA).\(^{3,4}\)
- Ceftriaxone is preferred to cefotaxime in all patients except neonates.

**INDICATIONS AND RESTRICTIONS**

**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.\(^{1,2,5,6}\)

**PRECAUTIONS**

- Rapid IV injection has resulted in life-threatening cardiac arrhythmias, ensure IV injections are given over a minimum of 3 to 5 minutes.\(^{1,2,7}\)
- 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.\(^{8}\)
## FORMULATIONS

<table>
<thead>
<tr>
<th>Available at PCH:</th>
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<tbody>
<tr>
<td>• 1gram powder for injection vial (DBL)</td>
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### Other formulations available:

<table>
<thead>
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<tbody>
<tr>
<td>• 500mg powder for injection vial (multiple generic brands).</td>
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<tr>
<td>• 2 gram powder for injection vial (multiple generic brands).</td>
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## 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 (<30 days postnatal life):

- Please refer to [neonatal clinical care drug protocols](#).

### IV:

- **Usual dose:** 25-50mg/kg/dose (to a maximum of 2gram) 8 hourly.<sup>(1, 9)</sup>
- **Severe infections(e.g. meningitis):** 50mg/kg/dose (to a maximum of 2grams) 6 hourly.<sup>(1, 9)</sup>

## DOSAGE ADJUSTMENT

### Dosage adjustment required in renal impairment:

- Dosage adjustment may be required in cases of impaired renal function (with creatinine clearance of less than 50 mL/min).
- To calculate the estimated glomerular filtration rate (eGFR) use the following formula:<sup>(3)</sup>

\[
eGFR (\text{mL/min/1.73m}^2) = \frac{36.5 \times \text{height (in cm)}}{\text{Serum creatinine (micromol/L)}}
\]

- 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.<sup>(8)</sup>

### 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.<sup>(2)</sup>

## RECONSTITUTION

### IV:

- Reconstitute each 1gram vial with 9.6mL of water for injection to give a final concentration of 100mg/mL.
- Further dilution may be required for administration (see below for further information).<sup>(7)</sup>
### ADMINISTRATION

<table>
<thead>
<tr>
<th>IV injection:</th>
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<tbody>
<tr>
<td>- Dilute to 100mg/mL or weaker and give by slow IV injection over 3 to 5 minutes.(^7)</td>
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<tr>
<td>- <strong>Note:</strong> life threatening arrhythmias have occurred with rapid IV injection (over 1 minute). Ensure IV injections are given over 3 to 5 minutes.(^1,2,7)</td>
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<table>
<thead>
<tr>
<th>IV infusion:</th>
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<tr>
<td>- Dilute to 40mg/mL or weaker with compatible fluid and infuse over 15 to 30 minutes.(^7)</td>
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</table>

### 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

<table>
<thead>
<tr>
<th>Common: diarrhea, nausea, vomiting, pain and inflammation at injection site, rash, headache, dizziness, allergy, <em>Clostridium difficile</em>-associated disease.(^1,5)</th>
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</thead>
<tbody>
<tr>
<td>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)</td>
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### 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 CIVAS between 2 and 8°C.
- Reconstituted solutions should be protected from light.
### INTERACTIONS

- Cefotaxime has few drug interactions; please consult PCH approved references, your ward pharmacist or **Pharmacy on 6456 0190 (option 1)** 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.\(^{(1)}\)
- Probenecid increase the half-life and prolongs the activity of cephalosporins, monitor for adverse effects.\(^{(1)}\)
- 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](#).**

**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


6. Micromedex 2.0 [Internet]. Truven Health Analytics. 2016 [cited 07/06/2016].


This document can be made available in alternative formats on request for a person with a disability.