MONOGRAPH

Ceftaroline 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

DRUG CLASS

Cephalosporin.[1]

INDICATIONS AND RESTRICTIONS

- Ceftaroline is indicated in the treatment of complicated skin and soft tissue infections and community acquired pneumonia.[1-3]
- Ceftaroline has good activity against Gram-positive aerobic bacteria (including Methicillin Resistant *Staph aureus* MRSA), with variable activity against Gram negative aerobic bacteria, and anaerobic bacteria . It does not cover *Pseudomonas aeruginosa*.[4]

IV: Restricted (red) antibiotic

ChAMP approval is required prior to prescription.

CONTRAINDICATIONS

- Hypersensitivity to ceftaroline, cephalosporins or any component of the formulation.[1, 5, 6]
- Hypersensitivity to L-arginine.[7]

PRECAUTIONS

- Ceftaroline may be prescribed in selected patients with high risk allergy to another Beta-lactam sub-class (e.g. some penicillins, carbapenems) in discussion with immunology.
- In patients with a previous low risk reaction to ceftaroline 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.
- Dose reduction may be required in renal impairment.[1-3, 7]
- Care should be taken in patients with seizure disorders due to limited information. Seizures may occur in patients with high ceftaroline levels, such as in renal impairment or with high dose therapy.[3, 6, 7]

FORMULATIONS

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

- 600mg vial for reconstitution

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

IV:

Neonates ≥34 weeks gestational age and infants < 2 months of age:

- 12 days postnatal age to < 2 months: 6mg/kg/dose every 8 hours[2, 6, 7]

Children:

- ≥ 2 months to < 2 years: 8mg/kg/dose every 8 hours
- ≥ 2 to <18 years
    - ≤33kg: 12mg/kg/dose (to a maximum of 400mg) 8 hourly
    - >33kg: 600mg 12 hourly[1, 2, 6, 7]

Higher doses may be used in cases of confirmed MRSA infections with an MIC of 2mg/L to 4mg/L:

- ≥ 2 months to < 2 years: 10mg/kg/dose 8 hourly
- ≥ 2 years to <18 years: 12mg/kg/dose (to a maximum of 600mg) 8 hourly[7]

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

Renal impairment:

- eGFR calculator (Google Chrome®)

Children 2 to <12 years and adolescents (12-18 years with bodyweight <33kg)[7]:

Creatinine clearance	Dose
>30 to ≤50mL/minute	8mg/kg/dose (to a maximum of 300mg) every 8 hours
≥15 to ≤30mL/minute	6mg/kg/dose (to a maximum of 200mg) every 8 hours
<15mL/minute	No information available, consider another agent.

Children 12 to 18 years and ≥ 33kg[7]:

Creatinine clearance	Dose
>30 to ≤50mL/minute	400mg 12 hourly
≥15 to ≤30mL/minute	300mg 12 hourly
<15mL or intermittent haamodialysis	200mg 12 hourly If on intermittent haemodialysis, ceftaroline should be administered after the haemodialysis session.

Hepatic impairment:

- No dosage adjustment is required for patients with hepatic impairment.[2, 6, 8]

RECONSTITUTION & ADMINISTRATION

Rapid IV administration of large doses may result in seizures.

Reconstitution:

- Reconstitute the vial with 19.3mL of water for injection to make a final concentration of 30mg/mL (powder volume 0.7mL). Further dilution will be required prior to administration.[5]

Administration:

- Dilute the required dose to a final concentration of 12mg/mL or less with compatible fluid and infuse over:
  - <2 months: 30 to 60 minutes.[2, 6]
  - ≥ 2 months: 5 to 60 minutes.[6, 7]
- For patients prescribed higher doses for confirmed MRSA infections with an MIC of 2mg/L to 4mg/L an infusion time of 120 minutes is recommended for all patients >2 months.[7]

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

Compatible fluids:

- Glucose 5%
- Glucose 2.5% with sodium chloride 0.45%
- Sodium chloride 0.9%

- Hartmann's
- Lactated Ringers.[2, 5, 7]

Compatible at Y-site:

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

MONITORING

- Patients should have a complete blood count and renal function conducted at baseline and then twice weekly for courses longer than 7 days.[1, 2, 6]
- Monitor the infusion site for all patients as infusion site reactions (e.g. erythema, phlebitis and pain) are common.[5]

ADVERSE EFFECTS

Common: neutropenia (more common if treated for longer than 2 weeks) diarrhoea, nausea, abdominal pain, eosinophilia, vomiting, pain and inflammation at the injection site, rash, headache, dizziness, allergy.[1, 3]

Infrequent: angioedema

Rare: neurotoxicity (e.g. confusion, seizures, encephalopathy) especially with high dose and/or renal impairment, anaemia, thrombocytopenia, agranulocytosis, haemolytic anaemia, severe cutaneous adverse reactions (SCARs), bleeding, renal impairment, immunologic reactions (drug fever, anaphylaxis, urticarial, interstitial nephritis, arthritis, serum sickness like syndrome).[1, 3]

STORAGE

- Store the vial below 25°C and protect from light.[5, 7]
- Store products prepared by Pharmacy Compounding Service (PCS) between 2 and 8°C[5, 7]

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 **ceftaroline**. 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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5. Symons K. Ermer J. (editors). Australian injectable drugs handbook. Collingwood: The Society of Hospital Pharmacists of Australia; 2020.
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