**MONOGRAPH**

**Ertapenem Monograph - Paediatric**

| Scope (Staff): | Medical, Nursing, Pharmacy |
| Scope (Area): | Perth Children’s Hospital (PCH) |

This document should be read in conjunction with this DISCLAIMER

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>• Ertapenem is a broad spectrum carbapenem antibiotic. It inhibits bacterial cell wall synthesis by binding to penicillin-binding proteins.(^{(1-4)})</th>
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</thead>
<tbody>
<tr>
<td>INDICATIONS AND RESTRICTIONS</td>
<td>• Ertapenem is active against many resistant enteric Gram-negative rods, anaerobes and many Gram-positive organisms. It has poor activity against <em>P. aeruginosa</em>, <em>Enterococcus</em> and <em>Acinetobacter</em> species and poor central nervous system (CNS) penetration.(^{(5)}) • Main use at PCH is for Hospital in the Home (HiTH) carbapenem therapy <strong>IV: Restricted (red) antibiotic</strong> • ChAMP approval is required prior to prescription. Contact the on-call ID Consultant or Fellow for approval PRIOR to prescribing. Document the indication, the ChAMP approver, and the date and time on the prescription or in the medication chart indication box.</td>
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<tr>
<td>CONTRAINDICATIONS</td>
<td>• Ertapenem is generally contraindicated in patients with a history of high risk allergy to carbapenems.</td>
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<td>PRECAUTIONS</td>
<td>• Ertapenem may be prescribed in selected patients with high risk allergy to another Beta-lactam sub-class (e.g. some penicillins and cephalosporins) in discussion with immunology. • In patients with a previous low risk reaction to ertapenem or another carbapenem (delayed rash [&gt;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.</td>
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<tr>
<td>FORMULATIONS</td>
<td>Available at PCH: • 1 gram powder for injection Other formulations available: • Nil</td>
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</tbody>
</table>
### 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 and infants under 3 months of age:**
- Not routinely used in neonates or infants < 3 months old; contact infectious diseases or clinical microbiology for advice.

**IV/IM:**
- **Usual dose:**
  - ≥ 3 months to <12 years: 15mg/kg/dose (to a maximum of 500mg) twice daily.\(^{(1, 4, 6, 7)}\)
  - ≥ 12 years: 1 gram once daily.\(^{(1, 4, 6, 7)}\)

### DOSAGE ADJUSTMENT

**Dosage adjustment required in renal impairment:**
- Dosage adjustment required in cases of impaired renal function with creatinine clearance (CrCl) of less than 30mL/min.
- To calculate the estimated glomerular filtration rate (eGFR) use the following formula (also available via the link)\(^{(5, 6)}\)

\[
eGFR = \frac{36.5 \times \text{height (cm)}}{\text{Serum creatinine (micromol/L)}}
\]

- CrCl ≥ 30mL/minute – normal dosing
- CrCl <30mL/minute – ≥ 12 years of age: 500mg once daily.\(^{(2-4, 7)}\)
- CrCl <30mL/minute – < 12 years of age: no data available, consider an alternative agent.\(^{(2, 7)}\)

**Dosage adjustment required in hepatic impairment:**
- No dosage adjustment is required for patients with hepatic impairment.\(^{(3)}\)

### RECONSTITUTION

**IV:**
- Reconstitute each 1 gram vial with 10mL of water for injection or sodium chloride 0.9% to make a 100mg/mL solution.\(^{(3, 8)}\)
- Shake well to dissolve. Dilute further to a concentration of 20mg/mL or less prior to administration.\(^{(3, 8)}\)

**IM:**
- Ertapenem may be given by intramuscular injection. Refer to product information for reconstitution instructions.\(^{(2, 8)}\)

### ADMINISTRATION

**IV infusion:**
- Dilute with compatible fluid to a concentration of 20mg/mL or less and infuse over 30 minutes.\(^{(1, 3, 6-8)}\)
**IM:**

- Ertapenem may be given by intramuscular injection. Refer to product information for administration instructions.\(^{(2, 8)}\)

**MONITORING**

- Renal, hepatic and haematological function should be monitored weekly with prolonged therapy (i.e. longer than 7 days).\(^{(1, 3, 4)}\) In patients with a history of seizures, neurological assessment should be considered.\(^{(4)}\)

**ADVERSE EFFECTS**

**Common:** nausea, vomiting, diarrhoea, headache, injection site reactions, raised platelet count.\(^{(1, 6)}\)

**Rare:** fever, fatigue, pain, hypotension, constipation, confusion, dizziness, dyspnoea, erythema, taste disturbance, tooth discoloration, altered liver function tests (LFT’s), neutropenia, seizures, hallucinations, aggression, delirium, *Clostridium difficile*-associated diarrhoea, anaphylaxis, itch, rash, dry mouth, anorexia, bradycardia, oedema.\(^{(1, 6)}\)

**COMPATIBLE FLUIDS**

- Water for injection\(^{(9)}\)
- Sodium chloride 0.9%\(^{(9)}\)
- Ertapenem is **INCOMPATIBLE** with glucose 5%, Hartmann’s, Mannitol, Ringer’s and sodium bicarbonate - IV lines should be flushed with sodium chloride 0.9% prior to administration.\(^{(6, 8)}\)

**STORAGE**

- Store vial below 25°C.\(^{(2, 4, 8)}\)

**INTERACTIONS**

Ertapenem 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.

- Carbapenems have been shown to significantly reduce the blood levels of sodium valproate with a consequent increase in seizures. Co-administration should be avoided.\(^{(2)}\)
- Concomitant use of warfarin may result in an increased international normalised ratio (INR) thereby potentiating the risk for bleeding. Monitor patients for signs and symptoms of bleeding and increase the monitoring of INR especially during initiation and discontinuation of the antibiotic.\(^{(2)}\)

**COMMENTS**

- Each gram of ertapenem contains approximately 137mg (6mmol) of sodium.\(^{(1, 7, 8)}\)

**MANUFACTURER SAFETY DATA SHEET (SDS)**

To access the Manufacturer SDS for this product, use the following link to [ChemAlert](#).

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**Please note:** The information contained in this guideline is to assist with the preparation and administration of ertapenem. Any variations to the doses recommended should be clarified with the prescriber prior to administration**
### Related CAHS internal policies, procedures and guidelines

<table>
<thead>
<tr>
<th>Policy/Protocol</th>
<th>Details</th>
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<tbody>
<tr>
<td><strong>Antimicrobial Stewardship Policy</strong></td>
<td></td>
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<tr>
<td><strong>ChAMP Empiric Guidelines and Monographs</strong></td>
<td></td>
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<tr>
<td><strong>KEMH Neonatal Medication Protocols</strong></td>
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### References and related external legislation, policies, and guidelines

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

File Path: W:\Safety & Quality\CAHS\CLOVERS MEDICAL Pharmacy\Procedures Protocols and Guidelines\ChAMP

Document Owner: Head of Department – Infectious Diseases

Reviewer / Team: Children’s Antimicrobial Management Program Pharmacist

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Approved by: Drug and Therapeutics Committee  Date: August 2020

Endorsed by: Chair, Drug and Therapeutics Committee  Date: August 2020

Standards Applicable:
- NSQHS Standards: 🌐🌐🌐
- NSMHS: N/A
- Child Safe Standards: N/A

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