### **MONOGRAPH**

# **Ertapenem 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					
<u>Dosage/Dosage</u> <u>Adjustments</u>	Administration	Compatibility	Monitoring		
DRUG CLACC					

### <u>DRUG CLASS</u>

Carbapenem antibiotic<sup>(1)</sup>

#### INDICATIONS AND RESTRICTIONS

# IV: Restricted (red) Antibiotic

ChAMP approval is required prior to prescription.

- Ertapenem is active against many resistant enteric Gram-negative rods, anaerobes and many Gram-positive organisms. It has poor activity against *Pseudomonas aeruginosa, Enterococcus* and *Acinetobacter* species and poor central nervous system (CNS) penetration. (1, 2)
- Ertapenem is inactive against Methicillin Resistant Staphylococcus aureus (MRSA), Vancomycin resistant Enterococci (VRE), *Enterococcus faecium*, Mycoplasma species, Chlamydia species and *Stenotrophomonas maltophilia*. (1, 2)

# **CONTRAINDICATIONS**

 Hypersensitivity to ertapenem, <u>high risk allergy</u> to carbapenems or any component of the formulation. (1, 3, 4)

### **PRECAUTIONS**

- 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 <u>low risk reaction</u> to ertapenem or another carbapenem (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. (1)
- Each gram of ertapenem contains approximately 137mg (6mmol) of sodium. (1, 5, 6)
- Avoid use in combination with sodium valproate when possible due to a significant reduction in the concentration of sodium valproate.<sup>(1, 4)</sup>
- Ertepenem should be used with caution in patients with CNS disorders as there is an increased risk of seizures. (4, 6)

#### **FORMULATIONS**

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

1gram powder for injection

Imprest location: Formulary One

#### **DOSAGE & DOSAGE ADJUSTMENTS**

# 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. (4, 7)

**Dosing in Overweight and Obese Children:** Dose based on measured body weight. (8)

### Renal impairment:

### eGFR calculator

CrCl ≥ 30mL/minute: normal dosing<sup>(1, 4, 6)</sup>

CrCl <30mL/minute: ≥ 12 years of age: 500mg once daily. (3, 4)

CrCl <30mL/minute: < 12 years of age: no data available, consider an alternative agent. (4)

### **Hepatic impairment:**

No dosage adjustment is required for patients with hepatic impairment. (4)

# RECONSTITUTION & ADMINISTRATION

#### IV infusion:

- Reconstitute each 1gram vial with 10mL of water for injection or sodium chloride 0.9% to make a solution of approximately 100mg/mL.<sup>(5, 9)</sup>
- Shake well to dissolve. Dilute further to a concentration of 20mg/mL or less and infuse over 30 minutes. (5, 9).

# IM injection:

Ertapenem may be given by intramuscular injection.

Reconstitute each 1gram vial with 3.2mL of lidocaine (lignocaine) 1% (10mg/mL) to make an approximate concentration of 250mg/mL. (5)

Note: Preparations with lidocaine (lignocaine) 1% (10mg/mL) as diluent must NEVER be given intravenously. (5, 9)

Doses up to 1gram may be injected into a large muscle mass. Refer to the <u>Intramuscular Injections Guideline</u> (internal link) for advice. (4, 5, 9)

# COMPATIBILITY (LIST IS NOT EXHAUSTIVE)

### Compatible fluids:

Water for injection<sup>(5)</sup>

Sodium chloride 0.9%<sup>(5)</sup>

### Compatible at Y-site:

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

### **INCOMPATIBLE drugs:**

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. (5)

#### **MONITORING**

Renal, hepatic and haematological function should be monitored weekly with prolonged therapy (i.e. longer than 7 days). In patients with a history of seizures, neurological assessment should be considered.<sup>(1, 4, 9)</sup>

# **ADVERSE EFFECTS**

**Common:** nausea, vomiting, diarrhoea, headache, injection site reactions (e.g. phlebitis). (1, 6)

**Infrequent:** itch, rash, hot flushes, melaena. *Clostridioides difficile*-associated diarrhoea, fever, fatigue, pain, hypotension, constipation, confusion, dizziness, dyspnoea, erythema, taste disturbance, altered liver function tests (LFT's), neutropenia.<sup>(1, 6)</sup>

Rare: seizures, hallucinations, aggression, delirium, anaphylaxis, tooth discolouration. (1, 6, 9)

### **STORAGE**

Store vial below 25°C.<sup>(5, 10)</sup>

# **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 **erapenem**. 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

- 1. Rossi S, editor. Australian Medicines Handbook. Adelaide, S. Aust.: Australian Medicines Handbook: 2022.
- 2. Antibiotic Writing Group. Therapeutic Guidelines Antibiotic. West Melbourne: Therapeutic Guidelines Ltd; 2019. Available from: <a href="https://tgldcdp-tg-org-au.pklibresources.health.wa.gov.au/etgAccess">https://tgldcdp-tg-org-au.pklibresources.health.wa.gov.au/etgAccess</a>.
- 3. McEvoy G, editor. AHFS Drug Information. Maryland: American Society of Health-System Pharmacists; 2022.
- 4. Ertapenem Pediatric drug information [Internet]. Lexicomp. 2022 [cited 24/05/2022].
- 5. Symons K. Ermer J. (editors). Australian injectable drugs handbook. Collingwood: The Society of Hospital Pharmacists of Australia; 2022.
- 6. Paediatric Formulary Committee. BNF for Children: 2022. London: BMJ Group Pharmaceutical Press; 2022.
- 7. Royal Australian College of General Practitioners, Pharmaceutical Society of Australia, Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists. AMH: Children's Dosing Companion. Adelaide: Australian Medicines Handbook Pty Ltd; 2022.
- 8. Kendrick JG, Carr RR, Ensom MHH. Pharmacokinetics and drug dosing in obese children. J Pediatr Pharmacol Ther. 2010;15(2):94-109.
- 9. Clinical Pharmacology [Internet]. Elsvier BV. 2022 [cited 13/06/2022]. Available from: <a href="http://www.clinicalpharmacology-ip.com.pklibresources.health.wa.gov.au/default.aspx">http://www.clinicalpharmacology-ip.com.pklibresources.health.wa.gov.au/default.aspx</a>.
- 10. MIMS Australia. MIMS online [full product information]. St Leonards, N.S.W: CMP Medica Australia.; 2021. p. 1v. (various pagings).

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

File Path:	W:\Paediatrics\PMH\ChAMP\Monographs\FINALISED\00 Current version 00			
Document Owner:	Head of Department – Infectious Diseases			
Reviewer / Team:	Children's Antimicrobial Management Program Pharmacist			
Date First Issued:	May 2013	Last Reviewed:	May 2022	
Amendment Dates:	July 2019, June 2020, May 2022	Next Review Date:	June 2025	
Approved by:	Drug and Therapeutics Committee	Date:	June 2022	
Endorsed by:	Chair, Drugs and Therapeutics Committee	Date:	June 2022	
Standards Applicable:	NSQHS Standards: Pick Color NSMHS: N/A Child Safe Standards: N/A			
Printed or personally saved electronic copies of this document are considered uncontrolled				
Healthu kids healthu communities				

Healthy kids, nealthy communities

Compassion

Excellence Collaboration Accountability

Respect

Neonatology | Community Health | Mental Health | Perth Children's Hospital