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

Dosage/Dosage Adjustments	Administration	Compatibility	Monitoring

DRUG CLASS

Carbapenem antibiotic.[1-4]

INDICATIONS AND RESTRICTIONS

IV: Protected (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.[3, 5, 6]
- Ertapenem is inactive against Methicillin Resistant Staphylococcus aureus (MRSA), Vancomycin resistant Enterococci (VRE), *Enterococcus faecium*, Mycoplasma species, Chlamydia species and *Stenotrophomonas maltophilia.*[3, 5]

CONTRAINDICATIONS

- Hypersensitivity to ertapenem, high risk allergy to carbapenems or any component of the formulation.[3, 6-8]

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 low risk reaction 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.[2, 3, 8, 9]
- Each gram of ertapenem contains approximately 137 mg (6 mmol) of sodium.[3, 6, 8, 10]
- Avoid use in combination with sodium valproate when possible due to a significant reduction in the concentration of sodium valproate.[3, 4, 6, 8]
- Ertapenem should be used with caution in patients with CNS disorders (e.g. a history of seizures) and/ or renal impairment as there is an increased risk of seizures.[7, 9, 10]

FORMULATIONS

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

- 1 gram 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: 15 mg/kg/dose (to a maximum of 500 mg) twice daily.[1, 3, 4, 8, 9]

≥ 12 years: 1 gram once daily.[1, 3, 4, 8, 9]

Dosing in Overweight and Obese Children: Dose based on measured body weight.[10, 11]

Renal impairment:

eGFR calculator

- Use ertapenem cautiously in patients with impaired renal function due to an increased risk of seizures.[3, 8, 9]

eGFR ≥ 30 mL/minute/1.73 m^2: normal dosing.[4]

eGFR <30 mL/minute/1.73 m^2: ≥ 12 years of age: 500 mg once daily.[4]

eGFR <30 mL/minute/1.73 m^2: < 12 years of age: no data available, consider an alternative agent.[4]

Hepatic impairment:

- No studies have been conducted in hepatic impairment, it appears no dosage adjustment is required.[4, 8]

RECONSTITUTION & ADMINISTRATION

Reconstitution – Intravenous:[2, 6, 12]

- Reconstitute each vial with the volume of water for injection in the table below. Further dilution with a compatible fluid may be required.

Brand	Volume of water for infection	Resulting concentration	Powder volume
Juno and Kabi	9.3 mL	100 mg/mL	0.7 mL
Invanz brand	10 mL	100 mg/mL	No information

Administration

IV infusion:

- Dilute to a final concentration of 20 mg/mL or weaker and infuse over 30 minutes.[2, 4, 6, 8]

Continuous infusion:

- Total daily dose may be given over 24 hours via continuous Baxter infusion.

Reconstitution – Intramuscular:[2, 6, 12]

Brand	Volume of lidocaine (lignocaine) 1%	Resulting concentration	Powder volume
Juno and Kabi	3.2 mL	250 mg/mL	0.8 mL
Invanz brand	3.2 mL	250 mg/mL	No information

Note: Preparations with lidocaine (lignocaine) 1% (10 mg/mL) as diluent must NEVER be given intravenously.[2, 8, 10]

Administration

IM injection:

Doses up to 1 gram may be injected into a large muscle mass. Refer to the Intramuscular Injections Guideline (internal link) for advice.[2, 4, 12]

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

Compatible fluids:

- Sodium chloride 0.9%[2, 10, 12]

INCOMPATIBLE fluids: Ertapenem is INCOMPATIBLE with glucose 5%, Hartmann's, Mannitol, Ringer's solution and sodium bicarbonate - IV lines should be flushed with sodium chloride 0.9% prior to administration.[2, 6, 10, 13]

Compatible at Y-site:

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

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.[3, 4, 7, 10, 13]

ADVERSE EFFECTS

Common: nausea, vomiting, diarrhoea, headache, injection site reactions (e.g. phlebitis).[3, 9]

Infrequent: itch, rash, hot flushes, melaena. *Clostridioides difficile*-associated disease, fever, fatigue, pain, hypotension, constipation, confusion, dizziness, dyspnoea, erythema, taste disturbance, altered liver function tests (LFT's), neutropenia.[3, 9]

Rare: seizures, hallucinations, changes in mental state, aggression, delirium, anaphylaxis, tooth discolouration. [3, 9]

STORAGE

- Store vial below 25°C.[2, 6, 8]

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

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