Summary of Product Characteristics

1. Name of the pharmaceutical product:
ETRANEM® Injection
Ertapenem for Injection 1g (Lyophilized)

2. Qualitative and quantitative composition:
Each vial contains:
Ertapenem Sodium
Eq.to Ertapenem.....1g
Excipients.....qs
(For the full list of excipients, see section 6.1)

3. Pharmaceutical form:
Lyophilized powder for injection.
A White to pale yellow lyophilized cake from powder filled in clear & colourless tubular glass vial.

4. Clinical particulars
4.1 Therapeutic indications
Treatment: Ertapenem is indicated in paediatric patients (3 months to 17 years of age) and in adults for the treatment of the following infections when caused by bacteria known or very likely to be susceptible to ertapenem and when parenteral therapy is required:

- Intra-abdominal infections
- Community acquired pneumonia.
- Acute gynecological infections
- Diabetic foot infections of the skin and soft tissue

Prevention: Ertapenem is indicated in adults for the prophylaxis of surgical site infection following elective colorectal surgery.
Consideration should be given to official guidance on the appropriate use of antibacterial agents.

4.2 Posology and method of administration Posology:
For Injection: Vial
Ertapenem for injection is a sterile lyophilized powder in a single-dose vial containing 1 g ertapenem for intravenous infusion or for intramuscular injection after reconstitution.
Do not mix or co-infuse Ertapenem for injection with other medications. Do not use diluents containing dextrose (a-D-glucose).
Ertapenem for injection should be infused over 30 minutes in both the Treatment and Prophylactic regimens.

Treatment regimen:
Adults and paediatric patients 13 years of age and older. The dosage should be 1 gram once a day intravenously or intramuscularly.

Patients 3 months to 12 years of age should be administered 15mg/kg twice daily (not to exceed 1 g/day intravenously or intramuscularly).
Intravenous infusion may be administered in adults and paediatrics for up to 14 days or intramuscular injection for up to 7 days.

Prophylactic Regimen in Adults:
Prophylaxis regimen for adults: 1 gram single dose given 1 hour prior to elective colorectal surgery.

Method of administration:
Adults and pediatric patients 13 years of age and older:
Preparation for intravenous administration:
DO NOT MIX OR CO-INFUSE ERTAPENEM FOR INJECTION WITH OTHER MEDICATIONS. DO NOT USE DILUENTS CONTAINING DEXTROSE (a-D-GLUCOSE). ERTAPENEM FOR INJECTION MUST BE RECONSTITUTED AND THEN DILUTED PRIOR TO ADMINISTRATION.
1. Reconstitute the contents of a 1 g vial of ertapenem for injection with 10 mL of one of the following: Water for Injection, 0.9% Sodium Chloride Injection or Bacteriostatic Water for Injection, using a syringe equiped with a 21-gauge or smaller diameter needle. NOTE: Use with a needleless IV system is not recommended.
2. Shake well to dissolve and immediately transfer contents of the reconstituted vial to 50 mL of 0.9% Sodium Chloride Injection.
3. Complete the infusion within 6 hours of reconstitution.

Preparation for intramuscular administration:
ERTAPENEM FOR INJECTION MUST BE RECONSTITUTED PRIOR TO ADMINISTRATION.
1. Reconstitute the contents of a 1 g vial of ertapenem for injection with 3.2 mL of 1.0% lidocaine HCI injection (without epinephrine). Shake vial thoroughly to form solution.
2. Immediately withdraw the contents of the vial and administer by deep intramuscular injection into a large muscle mass (such as the gluteal muscles or lateral part of the thigh).
3. The reconstituted IM solution should be used within 1 hour after preparation.
NOTE: THE RECONSTITUTED SOLUTION SHOULD NOT BE ADMINISTERED INTRAVENOUSLY.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients of the formulation listed in section 6.1
- Hypersensitivity to any other carbapenem antibacterial agent.
- Severe hypersensitivity (e.g., anaphylactic reaction, severe skin reaction) to any other type of beta-lactam antibacterial agent (e.g., penicillins or cephalosporins).

4.4 Special warnings and precautions for use

Hypersensitivity: Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients receiving therapy with beta-lactams. These reactions are more likely to occur in individuals with a history of sensitivity to multiple allergens. Before initiating therapy with ertapenem, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, other beta-lactams and other allergens. If an allergic reaction to ertapenem occurs, discontinue the therapy immediately. Serious anaphylactic reactions require immediate emergency treatment.

Superinfection: Prolonged use of ertapenem may result in overgrowth of non-susceptible organisms. Repeated evaluation of the patient's condition is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Antibiotic-associated colitis: Antibiotic-associated colitis and pseudomembranous colitis have been reported with ertapenem and may range in severity from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhoea subsequent to the administration of antibacterial agents. Discontinuation of therapy with ERTAPENEM and the administration of specific treatment for Clostridioides difficile should be considered. Medicinal products that inhibit peristalsis should not be given.

Seizures: Seizures have been reported during clinical investigation in adult patients treated with ertapenem (1 g once a day) during therapy or in the 14-day follow-up period. Seizures occurred most commonly in elderly patients and those with pre-existing central nervous system (CNS) disorders (e.g. brain lesions or history of seizures) and/or compromised renal function. Similar observations have been made in the post-marketing environment.

Encephalopathy: Encephalopathy has been reported with the use of ertapenem. If ertapenem-induced encephalopathy is suspected (e.g. myoclonus, seizures, altered mental status, depressed level of consciousness), discontinuation of ertapenem should be considered. Patients with renal impairment are at higher risk of ertapenem-induced encephalopathy and the resolution may be prolonged.

Concomitant use with valproic acid: The concomitant use of ertapenem and valproic acid/sodium valproate is not recommended. Sub-optimal exposure Based on the data available it cannot be excluded that in the few cases of surgical interventions exceeding 4 hours, patients could be exposed to sub-optimal ertapenem concentrations and consequently to a risk of potential treatment failure. Therefore, caution should be exercised in such unusual cases.

4.5 Interaction with other medicinal products and other forms of interaction

Interactions caused by inhibition of P-glycoprotein-mediated clearance or CYP-mediated clearance of medicinal products are unlikely.

Decreases in valproic acid levels that may fall below the therapeutic

range have been reported when valproic acid was co-administered with

carbapenem agents. The lowered valproic acid levels can lead to inadequate seizure control; therefore, concomitant use of ertapenem and valproic acid/sodium valproate is not recommended and alternative antibacterial or anti-convulsant therapies should be considered.

4.6 Pregnancy and lactation

Pregnancy: Ertapenem should not be used during pregnancy unless the potential benefit outweighs the possible risk to the foetus.

Breast-feeding: Ertapenem is excreted in human milk. Because of the potential for adverse reactions on the infant, mothers should not breastfeed their infants while receiving ertapenem.

4.7 Effects on ability to drive and use machines.

Ertapenem is unlikely to impair the ability to drive and use machines.

4.8 Undesirable effects

Following are the common side effects of Ertapenem injection but not everybody gets them:

Diarrhoea, nausea, vomiting, Rash, pruritus, Elevations in ALT, AST, alkaline phosphatase, Elevation in platelet count, Decreases in neutrophil count.

Most of these side effects do not require medical attention and will resolve gradually over time. However, you are advised to talk to your doctor if you experience these side effects persistently.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS)
https://pv.pharmacyboardkenya.org'.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Mechanism of action: Ertapenem inhibits bacterial cell wall synthesis following attachment to penicillin binding proteins (PBPs). In Escherichia coli, affinity strongest to PBPs 2 and 3.

5.2 Pharmacokinetic properties

Plasma concentrations: Average plasma concentrations of ertapenem following a single 30 minute intravenous infusion of a 1 g dose in healthy young adults (25 to 45 years of age) were 155 micrograms/mL (Cmax) at 0.5 hour post dose (end of infusion), 9 micrograms/mL at 12 hour post dose, and 1 microgram/mL at 24 hour post dose.

Distribution: Ertapenem is highly bound to human plasma

proteins. In healthy young adults (25 to 45 years of age), the protein binding of ertapenem decreases, as plasma concentrations increase, from approximately 95 % bound at an approximate plasma concentration of < 50

micrograms/mL to approximately 92 % bound at an approximate plasma concentration of155 micrograms/mL (average concentration achieved at the end of infusion following 1 g intravenously). The volume of distribution (VDSS) of ertapenem in adults is approximately 8 litres (0.11 litre/kg) and approximately 0.2 litre/kg in paediatric patients 3 months to 12 years of age and approximately 0.16 litre/kg in paediatric patients 13 to 17 years of age.

Biotransformation: In healthy young adults (23 to 49 years of age), after intravenous infusion of radiolabelled 1 g ertapenem, the plasma radioactivity consists predominantly (94 %) of ertapenem. The major metabolite of ertapenem is the ring-opened derivative formed by dehydropeptidase-l-mediated hydrolysis of the beta-lactam ring.

Elimination: Ertapenem is eliminated primarily by the kidneys. The mean plasma half-life in healthy young adults is approximately 4 hours and the plasma clearance is approximately 1.8 L/hour. The mean plasma half-life in paediatric patients 13 to 17 years of age is approximately 4 hours and approximately 2.5 hours in paediatric patients 3 months to 12 years of age. Following the administration of 1 g IV radiolabelled ertapenem to healthy young adults, approximately 80% is recovered in urine and 10% in feces. Of the 80% recovered in urine, approximately 38% is excreted as unchanged drug and approximately 37% as the ring-opened metabolite. In healthy young adults given a 1 g IV dose, the mean percentage of the administered dose excreted in urine was 17.4% during 0-2 hours post dose, 5.4% during 4-6 hours post dose, and 2.4% during 12-24 hours post dose.

5.3 Preclinical safety data
Not Available

6. Pharmaceutical particulars
6.1 List of Excipients:

- Mannitol
- Sodium bicarbonate

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 Months

6.4 Special precautions for storage
Store below 30°C. Protect from direct sunlight, heat & moisture.

6.5 Nature and contents of container
ETRANEM ® Injection is available in the pack of 20ml Vial with 10ml water for Injection as the diluent.

6.6 Special precautions for disposal and other handling
Any unused medicine product or waste material should be disposed of in accordance with the local requirements.

7. Marketing authorization holder

KRISHNA CHEMISTS LTD,
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P.O. BOX 3328-
00506 NAIROBI,
KENYA.

8. Marketing Authorization Number
ETRANEM® INJECTION
H2021/CTD6241/1832ER

9. Date of first authorization/renewal of the authorization
ETRANEM® INJECTION
Date of first authorization – 16th June 2020

10. Date of revision of the text
11/02/2025