2D Matrix Code may change as per Supplier's m/c requirement

ERTAPIK P1514407

ERTAPIK P1514407

Summary of Product Characteristics

ERTAPIK

Ertapenem 1 g Lyophilised powder for solution for injection or infusion

R_x only

1. NAME OF DRUG PRODUCT: *Ertapenem 1 g Lyophilised powder for solution for injection or infusion*

(Trade) Name of Product: *ERTAPIK*

Strength: *1 g*

Pharmaceutical Form:
Before Reconstitution : White to off white lyophilized cake or powder in a clear glass vial stoppered with grey double slotted rubber stopper and sealed with aluminum seal having white colour PP disc.

After Reconstitution : Clear colorless to pale yellow colour solution free from visible particles.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Ertapenem 1 g Lyophilised powder for solution for injection or infusion:
Each vial contains: Ertapenem Sodium equivalent to 1g Ertapenem.
This medicine contains 137.6 mg sodium (main component of cooking/table salt) in each 1 g. This is equivalent to 6.88 % of the recommended maximum daily dietary intake of sodium for an adult.

3. PHARMACEUTICAL DOSAGE FORM: *Powder for solution for injection or infusion.*

4. CLINICAL PARTICULARS:

4.1 Therapeutic indications:

Treatment
ERTAPIK is indicated for the treatment of patients with moderate to severe infections caused by susceptible strains of microorganisms, as well as initial empiric therapy prior to the identification of causative organisms in the infections listed below:

- *Complicated Intra-Abdominal Infections*
- *Complicated Skin and Skin Structure Infections including diabetic lower extremity and diabetic foot infections*
- *Community Acquired Pneumonia*
- *Complicated Urinary Tract Infections including pyelonephritis*
- *Acute Pelvic Infections including postpartum endomyometritis, septic abortion and post surgical gynecologic infections*

ERTAPIK is indicated for the treatment of pediatric patients with moderate to severe infections caused by susceptible strains of microorganisms, as well as initial empiric therapy prior to identification of causative organisms in the indications listed below:-

- *Complicated intra-abdominal infections*
- *Complicated skin and skin structure infections*
- *Community acquired pneumonia*
- *Acute pelvic infections including postpartum endomyometritis, septic abortion and surgical gynaecologic infections*

Prevention
ERTAPIK is indicated in adults for the prophylaxis of surgical site infection following elective colorectal surgery.

4.2 Posology and method of administration:

The usual dose of ERTAPIK in patients 13 years of age and older is 1 gram (g) given once a day. The usual dose of ERTAPIK in patients 3 months to 12 years of age is 15 mg/kg twice daily (not to exceed 1 g/day).

ERTAPIK may be administered by intravenous (IV) infusion or intramuscular (IM) injection. When administered intravenously, ERTAPIK should be infused over a period of 30 minutes.

Intramuscular administration of ERTAPIK may be used as an alternative to intravenous administration in the treatment of those infections for which intramuscular therapy is appropriate.

The usual duration of therapy with ERTAPIK is 3 to 14 days but varies by the type of infection and causative pathogen(s). (See INDICATIONS.) When clinically indicated, a switch to an appropriate oral antimicrobial may be implemented if clinical improvement has been observed.

In controlled clinical studies, patients were treated from 3 to 14 days. Total treatment duration was determined by the treating physician based on site and severity of the infection, and on the patient's clinical response. In some studies, treatment was converted to oral therapy at the discretion of the treating physician after clinical improvement had been demonstrated.

Prophylaxis of surgical site infection following elective colorectal surgery: To prevent surgical site infections following elective colorectal surgery in adults, the recommended dosage is 1 g IV administered as a single intravenous dose given 1 hour prior to the surgical incision.

Patients with renal insufficiency: ERTAPIK may be used for the treatment of infections in adult patients with renal insufficiency. In patients whose creatinine clearance is >30 mL/min/1.73 m^2, no dosage adjustment is necessary. Adult patients with advanced renal insufficiency (creatinine clearance ≤30 mL/min/1.73 m^2), including those on hemodialysis, should receive 500 mg daily. There are no data in pediatric patients with renal insufficiency.

Patients on Hemodialysis: In a clinical study, following a single 1 g IV dose of ertapenem given immediately prior to a hemodialysis session, approximately 30% of the dose was recovered in the dialysate. When adult patients on hemodialysis are given the recommended daily dose of 500 mg of ERTAPIK within 6 hours prior to hemodialysis, a supplementary dose of 150 mg is recommended following the hemodialysis session. If ERTAPIK is given at least 6 hours prior to hemodialysis, no supplementary dose is needed. There are no data in patients undergoing peritoneal dialysis or hemofiltration. There are no data in pediatric patients on hemodialysis.

*When only the serum creatinine is available, the following formula** may be used to estimate creatinine clearance. The serum creatinine should represent a steady state of renal function*

Males: (weight in kg) x (140-age in years)
(72) x serum creatinine (mg/100 mL)

Females: (0.85) x (value calculated for males)

No dosage adjustment is recommended in patients with impaired hepatic function.

The recommended dose of ERTAPIK can be administered without regard to age (13 years and older) or gender.

*** Cockcroft and Gault equation: Cockcroft DW, Gault MH. Prediction of creatinine clearance from serum creatinine. Nephron. 1976*

4.3 Contraindications:

ERTAPIK is contraindicated in patients with known hypersensitivity to any component of this product or to other drugs in the same class or in patients who have demonstrated anaphylactic reactions to beta-lactams.

Due to the use of lidocaine HCl as a diluent, ERTAPIK administered intramuscularly is contraindicated in patients with a known hypersensitivity to local anesthetics of the amide type and in patients with severe shock or heart block. (Refer to the prescribing information for lidocaine HCl.).

4.4 Special warnings and precautions for use:

Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients receiving therapy with beta-lactams. Before initiating therapy with Ertapik, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalsporins, carbapenems or other beta-lactam agents. If an allergic reaction occurs, Ertapik must be discontinued immediately and appropriate alternative therapy instituted.

These reactions are more likely to occur in individuals with a history of sensitivity to multiple allergens. There have been reports of individuals with a history of penicillin hypersensitivity who have experienced severe hypersensitivity reactions when treated with another beta-lactam. Before initiating therapy with ERTAPIK, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, carbapenems, other beta-lactams and other allergens. If an allergic reaction to ERTAPIK occurs, discontinue the drug immediately and institute appropriate alternative therapy. Serious anaphylactic reactions require immediate emergency treatment.

Seizures and other central nervous system (CNS) adverse experiences have been reported during treatment with ERTAPIK (see SIDE EFFECTS). During clinical investigations in adult patients treated with ERTAPIK (1 g once a day), seizures, irrespective of drug relationship, occurred in 0.5% of patients during study therapy plus 14-day follow-up period. These experiences have occurred most commonly in patients with CNS disorders (e.g., brain lesions or history of seizures) and/or compromised renal function. Close adherence to the recommended dosage regimen is urged, especially in patients with known factors that predispose to convulsive activity. Anticonvulsant therapy should be continued in patients with known seizure disorders. If focal tremors, myoclonus, or seizures occur, patients should be evaluated neurologically and the dosage of ERTAPIK re-examined to determine whether it should be decreased or discontinued.

Case reports in the literature have shown that co-administration of carbapenems, including ertapenem, to patients receiving valproic acid or divalproex sodium results in a reduction in valproic acid concentrations. The valproic acid concentrations may drop below the therapeutic range as a result of this interaction, therefore increasing the risk of breakthrough seizures. Increasing the dose of valproic acid or divalproex sodium may not be sufficient to overcome this interaction. The concomitant use of ertapenem and valproic acid/divalproex sodium is generally not recommended. Anti-bacterials other than carbapenems should be considered to treat infections in patients whose seizures are well controlled on valproic acid or divalproex sodium. If administration of ERTAPIK is necessary, supplemental anti-convulsant therapy should be considered (See DRUG INTERACTIONS.).

As with other antibiotics, prolonged use of ERTAPIK 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.

Pseudomembranous colitis has been reported with nearly all antibacterial agents, including ertapenem, and may range in severity from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents. Studies indicate that a toxin produced by Clostridium difficile is a primary cause of "antibiotic-associated colitis".

Caution should be taken when administering ERTAPIK intramuscularly, to avoid inadvertent injection into a blood vessel (see DOSAGE AND ADMINISTRATION).

Lidocaine HCl is the diluent for intramuscular administration of ERTAPIK. Refer to the prescribing information for lidocaine HCl.

4.5 Interaction with other medicinal products and other forms of interaction

When ertapenem is administered with probenecid, probenecid competes for active tubular secretion and thus inhibits the renal excretion of ertapenem. This leads to small but statistically significant increases in the elimination half-life (19%) and in the extent of systemic exposure (25%). No dosage adjustment is necessary when ertapenem is given with probenecid. Because of the small effect on half-life, the co-administration with probenecid to extend the half-life of ertapenem is not recommended.

In vitro studies indicate that ertapenem does not inhibit P-glycoprotein-mediated transport of digoxin or vinblastine and that ertapenem is not a substrate for P-glycoprotein-mediated transport. In vitro studies in human liver microsomes indicate ertapenem does not inhibit metabolism mediated by any of the six major cytochrome p450 (CYP) isoforms: 1A2, 2C9, 2C19, 2D6, 2E1 and 3A4. Drug interactions caused by inhibition of P-glycoprotein-mediated drug clearance or CYP-mediated drug clearance are unlikely. (See CLINICAL PHARMACOLOGY, Distribution and Metabolism.)

Other than with probenecid, no specific clinical drug interaction studies have been conducted.
Case reports in the literature have shown that co-administration of carbapenems, including ertapenem, to patients receiving valproic acid or divalproex sodium results in a reduction of valproic acid concentrations. The valproic acid concentrations may drop below the therapeutic range as a result of this interaction, therefore increasing the risk of breakthrough seizures. Although the mechanism of this interaction is unknown, data from in vitro and animal studies suggest that carbapenems may inhibit the hydrolysis of valproic acid's glucuronide metabolite (VPA-g) back to valproic acid, thus decreasing the serum concentrations of valproic acid. (See PRECAUTIONS.)

4.6 Fertility, pregnancy and lactation:

Pregnancy
There are no adequate and well-controlled studies in pregnant women. Ertapenem should be used during pregnancy only if the potential benefit justifies the potential risk to the mother and fetus.

Lactation
Ertapenem is excreted in human milk (see CLINICAL PHARMACOLOGY, Distribution). Caution should be exercised when Ertapenem is administered to a nursing woman.

4.7 Effects on ability to drive and use machines:
No studies on the effects of Ertapenem on the ability to drive and use machines have been performed.

4.8 Undesirable effects:
Adult Patients
The total number of patients treated with ertapenem in clinical studies was over 1900 of which over 1850 received a 1 g dose of ERTAPIK. Most adverse experiences reported in these clinical studies were described as mild to moderate in severity. Drug-related adverse experiences were reported in approximately 20% of patients treated with ertapenem. Ertapenem was discontinued due to adverse experiences thought to be drug-related in 1.3% of patients.

The most common drug-related adverse experiences reported during parenteral therapy in patients treated with ertapenem were diarrhea (4.3%), infused vein complication (3.9%), nausea (2.9%) and headache (2.1%).

The following drug-related adverse experiences were reported during parenteral therapy in adult patients treated with ertapenem:

Common (≥ 1/100, <1/10)	*Nervous system disorders*	*Headache*
	Vascular disorders	*Infused vein complication, phlebitis/ thrombophlebitis*
	Gastrointestinal disorders	*Diarrhea, nausea, vomiting*
Uncommon (>1/1000, <1/100)	*Nervous system disorders*	*Dizziness, somnolence, insomnia, seizure, confusion*
	Cardiac and vascular disorders	*Extravasation, hypotension*
	Respiratory, thoracic and mediastinal disorders	*Dyspnea*
	Gastrointestinal disorders	*Oral candidiasis, constipation, acid regurgitation, C. difficile- associated diarrhea, dry mouth, dyspepsia, anorexia*
	Skin and subcutaneous tissue disorders	*Erythema, pruritus*
	General disorders and administration site conditions	*Abdominal pain, taste perversion, asthenia/ fatigue, candidiasis, edema/swelling, fever, pain, chest pain*
	Reproductive system and breast disorders	*Vaginal pruritus*

In clinical studies, seizure was reported during parenteral therapy in 0.2% of patients treated with ertapenem, 0.3% of patients treated with piperacillin/tazobactam and 0% of patients treated with ceftriaxone.

In the majority of clinical studies, parenteral therapy was followed by a switch to an appropriate oral antimicrobial. During the entire treatment period and a 14 day post treatment follow-up period, drug-related adverse experiences in patients treated with ERTAPIK included those listed in the table above as well as rash and vaginitis at an incidence of ≥ 1.0% (common) and allergic reactions, malaise and fungal infections at an incidence of >0.1% but <1.0% (uncommon).

In a clinical study for the treatment of diabetic foot infections in which 289 adult diabetic patients were treated with ertapenem, the drug-related adverse experience profile was generally similar to that seen in previous clinical trials.

In a clinical study for the prophylaxis of surgical site infections following elective colorectal surgery in which 476 adult patients received a 1 g dose of ertapenem prior to surgery, the only drug-related adverse experience during parenteral therapy that was not seen in previous clinical trials was sinus bradycardia reported at an incidence of >0.1% but <1.0% (uncommon).

Pediatric Patients

The total number of pediatric patients treated with ertapenem in clinical studies was 384. The overall safety profile is comparable to that in adult patients. In clinical trials, the most common drug-related clinical adverse experiences reported during parenteral therapy were diarrhea (5.5%), infusion site pain (5.5%) and infusion site erythema (2.6%).

The following drug-related adverse experiences were reported during parenteral therapy in pediatric patients treated with ertapenem:

Common (≥ 1/100, <1/10)	*Gastrointestinal disorders*	*Diarrhoea, vomiting*
	General disorders and administration site conditions	*Infusion site erythema, infusion site pain, infusion site phlebitis, infusion site swelling*
	Skin and subcutaneous tissue disorders	*Rash*

Additional drug-related adverse experiences that were reported during parenteral therapy in >0.5% but <1.0% of patients treated with ERTAPIK in clinical studies include: infusion site induration, infusion site pruritus, infusion site warmth and phlebitis.

In the pediatric clinical studies, the majority of the patients had parenteral therapy followed by a switch to an appropriate oral antimicrobial. During the entire treatment period and a 14 day posttreatment follow-up period, drug-related adverse experiences in patients treated with ERTAPIK were no different than those listed above.

Post-Marketing Experience:

The following post-marketing adverse experiences have been reported:

Immune System: anaphylaxis including anaphylactoid reactions

Psychiatric Disorders: altered mental status (including agitation, aggression, delirium, disorientation, mental status changes)

Nervous System Disorders: depressed level of consciousness, dyskinesia, gait disturbance, hallucinations, myoclonus, tremor, encephalopathy (recovery may be prolonged in patients with renal impairment).

Gastrointestinal Disorders: teeth staining
Skin and Subcutaneous Tissue Disorders: Acute Generalized Exanthematous Pustulosis (AGEP), Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS syndrome), urticaria, hypersensitivity vasculitis Musculoskeletal and Connective Tissue Disorders: muscular weakness.

4.9 Overdose:
No specific information is available on the treatment of overdosage with Ertapenem. Intentional overdosing of Ertapenem is unlikely. Intravenous administration of Ertapenem at a 3 g daily dose for 8 days to healthy adult volunteers did not result in significant toxicity. In clinical studies in adults, inadvertent administration of up to 3 g in a day did not result in clinically important adverse experiences. In pediatric clinical studies, a single IV dose of 40 mg/kg up to a maximum of 2 g did not result in toxicity.

In the event of an overdose, Ertapenem should be discontinued and general supportive treatment given until renal elimination takes place.

Ertapenem can be removed by hemodialysis; however, no information is available on the use of hemodialysis to treat overdosage.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties:

Pharmacodynamic Properties:
Mechanism of Action
Ertapenem has in vitro activity against a wide range of gram positive and gram-negative aerobic and anaerobic bacteria. The bactericidal activity of ertapenem results from the inhibition of cell wall synthesis and is mediated through ertapenem binding to penicillin binding proteins (PBPs). In Escherichia coli, it has strong affinity toward PBPs 1a, 1b, 2, 3, 4 and 5 with preference for PBPs 2 and 3. Ertapenem has significant stability to hydrolysis by most classes of beta-lactamases, including penicillinases, and cephalosporinases and extended spectrum beta-lactamases, but not metallo-beta-lactamases

Pharmacokinetic properties:
Absorption
Ertapenem, reconstituted with 1% lidocaine HCl injection, USP (in saline without epinephrine), is well absorbed following IM administration at the recommended dose of 1 g. The mean bioavailability is approximately 92%. Following 1 g daily IM administration, mean peak plasma concentrations (Cmax) are reached in approximately 2 hours (Tmax).

Distribution
Ertapenem is highly bound to human plasma proteins. In healthy young adults, the protein binding of ertapenem decreases as plasma concentrations increase, from approximately 95% bound at an approximate plasma concentration of <100 mcg/mL to approximately 85% bound at an approximate plasma concentration of 300 mcg/mL.
Average plasma concentrations (mcg/mL) of ertapenem following a single 30 minute IV infusion of a 1 or 2 g dose and IM administration of a single 1 g dose in healthy young adults are presented in Table 1.

Table 1 -Plasma Concentrations of Ertapenem in Adults After Single Dose Administration

Dose/Route	*Average Plasma Concentrations (mcg/mL)*								
	0.5 hr	*1 hr*	*2 hr*	*4 hr*	*6 hr*	*8 hr*	*12 hr*	*18 hr*	*24 hr*
*1 g IV**	*155*	*115*	*83*	*48*	*31*	*20*	*9*	*3*	*1*
1 g IM	*33*	*53*	*67*	*57*	*40*	*27*	*13*	*4*	*2*
*2 g IV**	*283*	*202*	*145*	*86*	*58*	*36*	*16*	*5*	*2*

**IV doses were infused at a constant rate over 30 minutes.*

Area under the plasma concentration curve (AUC) of ertapenem in adults increases nearly dose-proportionally over the 0.5 to 2 g dose range.

There is no accumulation of ertapenem in adults following multiple IV doses ranging from 0.5 to 2 g daily or IM doses of 1 g daily.

Average plasma concentrations (mcg/mL) of ertapenem in pediatric patients are presented in Table 2.

Table 2
Plasma Concentrations of Ertapenem in Pediatric Patients After Single IV* Dose Administration

Age Group (Dose)	Average Plasma Concentrations (mcg/mL)							
	0.5 hr	1 hr	2 hr	4 hr	6 hr	8 hr	12 hr	24 hr
3 to 23 months								
(15 mg/kg)†	103.8	57.3	43.6	23.7	13.5	8.2	2.5	-
(20 mg/kg†	126.8	87.6	58.7	28.4	-	12.0	3.4	0.4
(40 mg/kg)‡	199.1	144.1	95.7	58.0	-	20.2	7.7	0.6
2 to 12 years								
(15 mg/kg)†	113.2	63.9	42.1	21.9	12.8	7.6	3.0	-
(20 mg/kg)†	147.6	97.6	63.2	34.5	-	12.3	4.9	0.5
(40 mg/kg)‡	241.7	152.7	96.3	55.6	-	18.8	7.2	0.6
13 to 17 years								
(20 mg/kg)†	170.4	98.3	67.8	40.4	-	16.0	7.0	1.1
(1 g)§	155.9	110.9	74.8	-	24.0	-	6.2	-
(40 mg/kg)‡	255.0	188.7	127.9	76.2	-	31.0	15.3	2.1

*** IV doses were infused at a constant rate over 30 minutes.**
† up to a maximum dose of 1 g/day
‡ up to a maximum dose of 2 g/day
§ Based on three patients receiving 1 g ertapenem who volunteered for pharmacokinetic assessment in one of the two safety and efficacy studies

The volume of distribution (Vdss) of ertapenem in adults is approximately 8 liters (0.11 liter/kg) and approximately 0.2 liter/kg in pediatric patients 3 months to 12 years of age and approximately 0.16 liter/kg in pediatric patients 13 to 17 years of age.

Black A/s: 340 x 590 mm Drawing No: 9920674-007 or 9921333-002

eugia Packaging Development	Product: ERTAPIK	Component: Leaflet	Item Code: P1514407	Date & Time: 12.02.2026 & 7:30 PM
	Customer / Country: Malaysia_Eugia Unit 2	Version No.: 12	Reason Of Issue: Commercial	Reviewed / Approved by
Team Leader: Ariff	Dimensions: 340 x 590 mm	No. of Colours : 01		
Initiator: Vijay				
Artist: Vision Graphic Designers	2D code: P1514407			
Additional Information :				Sign / Date

Ertapenem penetrates into suction-induced skin blisters. Concentrations of ertapenem achieved in skin blister fluid at each sampling point on the third day of 1 g once daily IV doses are presented in Table 3. The ratio of AUC in skin blister fluid to AUC in plasma is 0.61.

Table 3
Concentrations (mcg/mL) of Ertapenem in Adult Skin Blister Fluid at Each Sampling Point on the Third Day of 1-g Once Daily IV Doses

0.5 hr	1 hr	2 hr	4 hr	8 hr	12 hr	24 hr
7	12	17	24	24	21	8

The level of ertapenem in breast milk of 5 lactating women was measured at random time points daily for 5 consecutive days following the last 1 g dose of intravenous therapy. The measured concentration of ertapenem in breast milk on the last day of therapy (5 to 14 days postpartum) in all 5 women was < 0.38 mcg/mL; peak concentrations were not assessed. By day 5 after discontinuation of therapy, the level of ertapenem was undetectable in the breast milk of 4 women and was detected at trace levels (< 0.13 mcg/mL) in 1 woman.

In vitro studies indicate that ertapenem does not inhibit P-glycoprotein-mediated transport of digoxin or vinblastine and that ertapenem is not a substrate for P-glycoprotein-mediated transport (see DRUG INTERACTIONS).

Metabolism

In healthy young adults, after IV infusion of radiolabeled 1 g ertapenem, the plasma radioactivity consists predominantly (94%) of ertapenem. The major metabolite of ertapenem is the ring- opened derivative formed by hydrolysis of the beta-lactam ring.

In vitro studies in human liver microsomes indicate that ertapenem does not inhibit metabolism mediated by any of the six major cytochrome p450 (CYP) isoforms: 1A2, 2C9, 2C19, 2D6, 2E1 and 3A4 (see DRUG INTERACTIONS).

Elimination

Ertapenem is eliminated primarily by the kidneys. The mean plasma half-life in healthy young adults and patients 13 to 17 years of age is approximately 4 hours and approximately 2.5 hours in pediatric patients 3 months to 12 years of age.

Following administration of a 1 g radiolabeled IV dose of 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, average concentrations of ertapenem in urine exceed 984 mcg/mL during the period 0 to 2 hours postdose and exceed 52 mcg/mL during the period 12 to 24 hours postdose.

PHARMACEUTICAL PARTICULARS

6.1 List of excipients:
Sodium Bicarbonate
Sodium Hydroxide

6.2 Incompatibilities:
Do not mix or co-infuse Ertapenem with other medications. Do not use diluents containing dextrose (α-D-Glucose).

6.3 Shelf life:
Please refer outer package for expiry date.

6.4 Storage Condition:
Before reconstitution
Do not store lyophilized powder above 30°C.

Reconstituted and infusion solutions
The reconstituted solution, immediately diluted in 0.9% Sodium Chloride Injection (see DOSAGE AND ADMINISTRATION, INSTRUCTIONS FOR USE), may be stored at room temperature (25°C) and used within 6 hours or stored for 24 hours under refrigeration (5°C) and used within 4 hours after removal from refrigeration. Solution of ERTAPIK should not be frozen.

6.5 Directions for use:
INSTRUCTIONS FOR USE
Patients 13 years of age and older

Preparation for intravenous administration:
DO NOT MIX OR CO-INFUSE ERTAPIK WITH OTHER MEDICATIONS.

DO NOT USE DILUENTS CONTAINING DEXTROSE (α-D-GLUCOSE).

ERTAPIK MUST BE RECONSTITUTED AND THEN DILUTED PRIOR TO ADMINISTRATION.

1. *Reconstitute the contents of a 1 g vial of ERTAPIK with 10 mL of one of the following: Water for Injection, 0.9% Sodium Chloride Injection or Bacteriostatic Water for Injection.*
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:

ERTAPIK MUST BE RECONSTITUTED PRIOR TO ADMINISTRATION.

1. *Reconstitute the contents of a 1 g vial of ERTAPIK with 3.2 mL of 1.0% or 2.0% lidocaine HCl 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.*

Pediatric patients 3 months to 12 years of age

Preparation for intravenous administration:
DO NOT MIX OR CO-INFUSE ERTAPIK WITH OTHER MEDICATIONS.

DO NOT USE DILUENTS CONTAINING DEXTROSE (α-D-GLUCOSE).

ERTAPIK MUST BE RECONSTITUTED AND THEN DILUTED PRIOR TO ADMINISTRATION.

1. *Reconstitute the contents of a 1 g vial of ERTAPIK with 10 mL of one of the following: Water for Injection, 0.9% Sodium Chloride Injection or Bacteriostatic Water for Injection.*
2. *Shake well to dissolve and immediately withdraw a volume equal to 15 mg/kg of body weight (not to exceed 1 g/day) and dilute in 0.9% Sodium Chloride Injection to a final concentration of 20 mg/mL or less.*
3. *Complete the infusion within 6 hours of reconstitution.*

Preparation for intramuscular administration:

ERTAPIK MUST BE RECONSTITUTED PRIOR TO ADMINISTRATION.

1. *Reconstitute the contents of a 1 g vial of ERTAPIK with 3.2 mL of 1.0% or 2.0% lidocaine HCl injection*** *(without epinephrine). Shake vial thoroughly to form solution.*
2. *Immediately withdraw a volume equal to 15 mg/kg of body weight (not to exceed 1 g/day) 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.*

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to use, whenever solution and container permit. Solutions of ERTAPIK range from colorless to pale yellow. Variations of color within this range do not affect the potency of the product.

6.6 Nature and contents of container:
Ertapenem 1 g Lyophilised powder for solution for injection or infusion: *Clear glass vial stoppered with grey double slotted rubber stopper and sealed with aluminium seal having Polypropylene disc.*

Ertapenem is supplied as a sterile lyophilized powder in single dose vials.

6.7 Special precautions for disposal and handling:

Each vial is for single use only.

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Manufactured by
Eugia Pharma Specialities Limited,
Unit-2, A-1128 B 1127, RIICO Industrial Area
Phase-III, District Khairthal Tijara ,Bhiwadi-301019,India.

Product Registration Holder
Healol Pharmaceuticals Sdn Bhd.
74-3, Jalan Wangsa Delima 6,
KLSC Wangsa Maju,
53300 Kuala Lumpur.

7. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
August 2025.

*** Refer to the prescribing information for lidocaine HCl.

P1514407