ERTAPIK P1527508

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Summary of Product Characteristics
ERTAPIK
Ertapenem for Injection 1 g
R_x only

NAME OF DRUG PRODUCT: ERTAPIK FOR INJECTION 1G (ERTAPENEM)
(TRADE) NAME OF PRODUCT: ERTAPIK
STRENGTH: 1 g

PHARMACEUTICAL FORM:
White to off white lyophilized cake or powder.

QUALITATIVE AND QUANTITATIVE COMPOSITION:
Ertapenem for Injection 1 g:
Each vial contains: Ertapenem Sodium equivalent to 1g Ertapenem.

PHARMACEUTICAL DOSAGEFORM: Powder for solution for injection or infusion.

CLINICAL PARTICULARS:
Therapeutic indications:
Ertapenem is indicated for the treatment of patients with the following moderate to severe infections caused by susceptible isolates of the designated microorganisms.

- Complicated Intra-abdominal Infections
- Complicated Skin and Skin Structure Infections including diabetic foot infections without osteomyelitis.
- Community Acquired Pneumonia.
- Complicated Urinary Tract Infections including pyelonephritis.
- Acute Pelvic Infections including postpartum endomyometritis, septic abortion and post surgical gynecologic infections.

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.

Posology and method of administration:
Posology:
The dose of Ertapenem in patients 13 years of age and older is 1 gram (g) given once a day. The dose of Ertapenem in patients 3 months to 12 years of age is 15 mg/kg twice daily (not to exceed 1 g/day). Ertapenem is not recommended in children under 3 months of age, as no data are available.

Method of administration:
Ertapenem may be administered by intravenous infusion for up to 14 days or intramuscular injection for up to 7 days. When administered intravenously, Ertapenem should be infused over a period of 30 minutes.

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

DO NOT MIX OR CO-INFUSE ERTAPENEM WITH OTHER MEDICATIONS. DO NOT USE DILUENTS CONTAINING DEXTROSE (α-D-GLUCOSE).

Table 1: Treatment Guidelines for Adults and Pediatric Patients with Normal Renal Function* and Body Weight

Infection†	Daily Dose (IV or IM) Adults and Pediatric Patients 13 years of age and older	Daily Dose (IV or IM) Pediatric Patients 3months to 12 years of age	Recommended Duration of Total Antimicrobial Treatment
Complicated intra-abdominal infections	1g	15 mg/kg twice daily‡	5 to 14 days
Complicated skin and skin structure infections, including diabetic foot infections§	1g	15 mg/kg twice daily‡	7 to 14 days
Community acquired pneumonia	1g	15 mg/kg twice daily‡	10 to 14 days#
Complicated urinary tract infections, including pyelonephritis	1g	15 mg/kg twice daily‡	10 to 14 days#
Acute pelvic infections including postpartum endomyometritis, septic abortion and post surgical gynecologic infections	1g	15 mg/kg twice daily‡	3 to 10 days

*defined as creatinine clearance >90 mL/min/1.73 m 2
†due to the designated pathogens
‡not to exceed 1 g/day
§Ertapenem has not been studied in diabetic foot infections with concomitant osteomyelitis.
#duration includes a possible switch to an appropriate oral therapy, after at least 3 days of parenteral therapy, once clinical improvement has been demonstrated.

Table 2: Prophylaxis guidelines for Ertapenem

Indication	Daily Dose (IV) Adults	Recommended Duration of Total Antimicrobial Treatment
Prophylaxis of surgical site infection following elective colorectal surgery	1 g	Single intravenous dose given 1 hour prior to surgical incision

Patients with Renal Insufficiency: Ertapenem 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 m2, no dosage adjustment is necessary. Adult patients with advanced renal insufficiency (creatinine clearance ≤30mL/min/1.73 m2) including those on haemodialysis should receive 500 mg daily. There are no data in pediatric patients with renal insufficiency.

Patients on Hemodialysis: When adult patients on hemodialysis are given the recommended daily dose of 500 mg of Ertapenem within 6 hours prior to hemodialysis, a supplementary dose of 150 mg is recommended following the hemodialysis session. If ERTAPENEM 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)

Patients with Hepatic Insufficiency: No dose adjustment recommendations can be made in patients with impaired hepatic function.

No dosage adjustment is recommended based on age (13 years of age and older) or gender.

Contraindications:
Ertapenem 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, Ertapenem 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.).

Special warnings and precautions for use:
Warnings
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. 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 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 drug immediately. Serious anaphylactic reactions require immediate emergency treatment with epinephrine, oxygen, intravenous steroids, and airway management, including intubation. Other therapy may also be administered as indicated.

Seizure Potential
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 ERTAPENEM is necessary, supplemental anti-convulsant therapy should be considered (See DRUG INTERACTIONS.).

Seizures and other central nervous system (CNS) adverse experiences have been reported during treatment with ERTAPENEM (see ADVERSE REACTIONS). During clinical investigations in adult patients treated with ERTAPENEM (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 ERTAPENEM re-examined to determine whether it should be decreased or discontinued.

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Ertapenem, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of Clostridium difficile.

Clostridium difficile produces toxins A and B which contribute to the development of CDAD. Hyper toxin producing strains of Clostridium difficile cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against Clostridium difficile may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of Clostridium difficile, and surgical evaluation should be instituted as clinically indicated.

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

Precautions
General
Dosage adjustment of Ertapenem is recommended in patients with reduced renal function.

As with other antibiotics, prolonged use of Ertapenem may result in overgrowth of non-susceptible organisms. Repeated evaluation of the patient's condition is essential. If super infection occurs during therapy, appropriate measures should be taken.

Prescribing Ertapenem in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

Caution should be taken when administering Ertapenem intramuscularly to avoid inadvertent injection in to a blood vessel.

Lidocaine HCl is the diluent for intramuscular administration of Ertapenem. Refer to the prescribing information for lidocaine HCl for additional precautions.

Interaction with other medicinal products and other forms of interaction
When Ertapenem is co-administered with probenecid (500 mg p.o. every 6 hours), probenecid competes for active tubular secretion and reduces the renal clearance of Ertapenem. Based on total Ertapenem concentrations, probenecid increased the AUC by 25% and reduced the plasma and renal clearances by 20% and 35%, respectively. The half-life increased from 4.0 to 4.8 hours. 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 that Ertapenem does not inhibit metabolism mediated by any of the following six cytochrome p450 (CYP) iso forms: 1A2, 2C9, 2C19, 2D6, 2E1 and 3A4. Drug interactions caused by inhibition of P-glycoprotein-mediated drug clearance or CYP-mediated drug clearance with the listed isoforms are unlikely.

Other than with probenecid, no specific clinical drug interaction studies have been conducted.

A clinically significant reduction in serum valproic acid concentration has been reported in patients receiving carbapenem antibiotics and may result in loss of seizure control. Although the mechanism of this interaction is not fully understood, data from in vitro and animal studies suggest that carbapenem antibiotics may inhibit valproic acid glucuronide hydrolysis. Serum valproic acid concentrations should be monitored frequently after initiating carbapenem therapy. Alternative antibacterial or anticonvulsant therapy should be considered if serum valproic acid concentrations drop below the therapeutic range or a seizure occurs.

Pregnancy and Lactation:
Pregnancy
For Ertapenem, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, Ertapenem should be used during pregnancy only if clearly needed.

Breast-feeding
Ertapenem is excreted in human breast milk. Caution should be exercised when Ertapenem is administered to a nursing woman. Ertapenem should be administered to nursing mothers only when the expected benefit outweighs the risk.

Fertility
There are no adequate and well-controlled studies regarding the effect of Ertapenem use on fertility in men and women. Preclinical studies do not indicate direct or indirect harmful effects with respect to fertility.

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. Ertapenem may influence patient's ability to drive and use machines. Patients should be informed that dizziness and somnolence have been reported with Ertapenem.

Undesirable effects:

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

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

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

Overdose:
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.

PHARMACOLOGICAL PROPERTIES:
Pharmacodynamic properties:
Ertapenem has in vitro activity against 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 is stable against hydrolysis by a variety of beta-lactamases, including penicillinases, and cephalosporinases and extended spectrum beta-lactamases. Ertapenem is hydrolyzed by metallo-beta-lactamases.

Ertapenem has been shown to be active against most isolates of the following microorganisms *in vitro* and in clinical infections.

Aerobic and facultative gram-positive microorganisms:
Staphylococcus aureus (methicillin susceptible isolates only)
Streptococcus agalactiae
Streptococcus pneumoniae (penicillin susceptible isolates only)
Streptococcus pyogenes
Note: Methicillin-resistant staphylococci and Enterococcus spp. are resistant to Ertapenem.

Aerobic and facultative gram-negative microorganisms:
Escherichia coli
Haemophilus influenzae (Beta-lactamase negative isolates only)
Klebsiella pneumoniae

Moraxella catarrhalis

Anaerobic microorganisms:
Bacteroides fragilis and other species in the B. fragilis Group
Clostridium species (excluding C. difficile)
Eubacterium lentum
Peptostreptococcus species
Porphyromonas asaccharolytica
Prevotella bivia

The following in vitro data are available, but their clinical significance is unknown.

At least 90% of the following microorganisms exhibit an in vitro minimum inhibitory concentration (MIC) less than or equal to the susceptible breakpoint for Ertapenem; however, the safety and effectiveness of Ertapenem in treating clinical infections due to these microorganisms have not been established in adequate and well-controlled clinical studies:

Aerobic and facultative gram-positive microorganisms:
Staphylococcus epidermidis (methicillin susceptible isolates only)
Streptococcus pneumoniae (penicillin-intermediate isolates only)

Aerobic and facultative gram-negative microorganisms:
Citrobacter freundii
Citrobacter koseri
Enterobacter aerogenes
Enterobacter cloacae
Haemophilus influenzae (Beta-lactamase positive isolates)
Haemophilus parainfluenzae
Klebsiella oxytoca (excluding ESBL producing isolates)
Morganella morganii
Proteus mirabilis
Proteus vulgaris
Providencia rettgeri
Providencia stuartii
Serratia marcescens

Anaerobic microorganisms:
Bacteroides vulgatus
Clostridium perfringens
Fusobacterium spp.

Pharmacokinetic properties
Absorption
Ertapenem, reconstituted with 1% lidocaine HCl injection, USP (in saline without epinephrine), is almost completely absorbed following intramuscular (IM) administration at the recommended dose of 1g. The mean bioavailability is approximately 90%. Following 1 g daily IM administration, mean peak plasma concentrations (Cmax) are achieved in approximately 2.3 hours (Tmax).

Distribution
Ertapenem is highly bound to human plasma proteins, primarily albumin. 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 micrograms (mcg)/mL to approximately 85% bound at an approximate plasma concentration of 300 mcg/mL.

Metabolism
In healthy young adults, after infusion of 1 g IV radio labeled Ertapenem, the plasma radio activity consists predominantly (94%) of Ertapenem. The major metabolite of Ertapenem is the inactive 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 following cytochrome p450 (CYP) isoforms: 1A2, 2C9, 2C19, 2D6, 2E1 and3A4.

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.

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 pediatric 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 the administration of 1 g IV radio labeled 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.

Special Populations
Renal Insufficiency
Total and unbound fractions of Ertapenem pharmacokinetics were investigated in 26 adult subjects (31 to 80 years of age) with varying degrees of renal impairment. Following a single 1 g IV dose of Ertapenem, the unbound AUC increased 1.5-fold and 2.3-fold in subjects with mild renal insufficiency (CLCR 60-90 mL/min/1.73 m2) and moderate renal insufficiency (CLCR 31-59 mL/min/1.73 m2), respectively, compared with healthy young subjects (25 to 45 years of age). No dosage adjustment is necessary in patients with CLCR≥31 mL/min/1.73 m2. The unbound AUC increased 4.4-fold and7.6-fold in subjects with advanced renal insufficiency (CLCR 5-30 mL/min/1.73 m2) and end-stage renal insufficiency (CLCR<10 mL/min/1.73 m2), respectively, compared with healthy young subjects.

The effects of renal insufficiency on AUC of total drug were of smaller magnitude. The recommended dose of Ertapenem in adult patients with CLCR≤30 mL/min/1.73 m2 is 0.5 grams every 24 hours.

Following a single 1 g IV dose given immediately prior to a 4 hour hemodialysis session in 5 adult patients with end-stage renal insufficiency, approximately 30% of the dose was recovered in the dialysate. A supplementary dose of 150 mg is recommended if Ertapenem is administered within 6 hours prior to hemodialysis. There are no data in pediatric patients with renal insufficiency.

Hepatic Insufficiency
The pharmacokinetics of Ertapenem in patients with hepatic insufficiency have not been established.

However, Ertapenem does not appear to undergo hepatic metabolism based on in vitro studies and approximately 10% of an administered dose is recovered in the feces.

Gender
The effect of gender on the pharmacokinetics of Ertapenem was evaluated in healthy male (n=8) and healthy female (n=8) subjects. The differences observed could be attributed to body size when body weight was taken into consideration. No dose adjustment is recommended based on gender.

Geriatric Patients
The impact of age on the pharmacokinetics of Ertapenem was evaluated in healthy male (n=7) and healthy female (n=7) subjects _65 years of age. The total and unbound AUC increased 37% and 67%, respectively, in elderly adults relative to young adults. These changes were attributed to age-related changes in creatinine clearance. No dosage adjustment is necessary for elderly patients with normal (for their age) renal function.

Pediatric Patients
Plasma concentrations of Ertapenem are comparable in pediatric patients 13 to 17 years of age and adults following a 1 g once daily IV dose.

Following the 20 mg/kg dose (up to a maximum dose of 1 g), the pharmacokinetic parameter values in patients 13 to 17 years of age (N=6) were generally comparable to those in healthy young adults.

Plasma concentrations at the midpoint of the dosing interval following a single 15 mg/kg IV dose of Ertapenem in patients 3 months to 12 years of age are comparable to plasma concentrations at the midpoint of the dosing interval following a 1 g once daily IV dose in adults. The plasma clearance (mL/min/kg) of Ertapenem in patients 3 months to 12 years of age is approximately2-fold higher as compared to that in adults. At the 15 mg/kg dose, the AUC value (doubled to model a twice daily dosing regimen, i.e., 30 mg/kg/day exposure) in patients 3 months to 12 years of age was comparable to the AUC value in young healthy adults receiving a 1 g IV dose of Ertapenem.

PHARMACEUTICAL PARTICULARS
List of excipients:
Sodium Bicarbonate
Sodium Hydroxide

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

Shelf life:
Please refer outer package for expiry date.

Storage Condition:
Before reconstitution
Store at or below 30ºC.

Reconstituted and infusion solutions
The reconstituted solution, immediately diluted in 0.9% Sodium Chloride Injection 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. Solutions of Ertapenem should not be frozen.

Directions for use:
Adults and pediatric patients 13 years of age and older:
Preparation of intravenous administration:
Ertapenem must be reconstituted and then diluted prior to administration.
1. Reconstitute the contents of a 1 g vial of Ertapenem 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:
Ertapenem must be reconstituted prior to administration.
1. Reconstitute the contents of a 1 g vial of Ertapenem with 3.2 mL of 1.0% lidocaine HCl injection (without epinephrine). Shake well 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 muscle 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 of intravenous administration:
Ertapenem must be reconstituted and then diluted prior to administration.
1. Reconstitute the contents of a 1 g vial of Ertapenem 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 with draw 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:
Ertapenem must be reconstituted prior to administration.
1. Reconstitute the contents of a 1 g vial of Ertapenem with 3.2 mL of 1.0% lidocaine HCl injection (without epinephrine). Shake well thoroughly to form solution.
2. Immediately with draw 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 muscle or lateral part of the thigh).
3. The reconstituted IM solution should be used with in 1 hour after preparation.

Note: The reconstituted solution should not be administered intravenously.

The reconstituted solutions should be inspected visually for particulate matter and discoloration prior to administration, whenever the container permits. Solutions of Ertapenem range from colorless to pale yellow. Variations of color within this range do not affect the potency of the product.

Nature and contents of container:
Ertapenem for Injection 1 g: Clear glass vial stoppered with grey double slotted rubber stopper and sealed with aluminum seal having white color PP disc.

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

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.

Manufactured by
Eugia Pharma Specialities Limited,
Unit-2, A-1128, RIICO Industrial Area, Phase-III,
Bhiwadi-301019, District - Alwar,
Rajasthan, India.

DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
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