

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 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 AUC (25%). No dosage adjustment is necessary when Ertapenem is given with probenecid. Because of the small effect on half-life, the coadministration with probenecid to extend the half-life of Ertapenem is not recommended.			
ADVERSE REACTIONS			
Local adverse reactions : Infused vein complication, Phlebitis/thrombophlebitis, Infusion site erythema, Infusion site pain, Infusion site swelling			
Systemic adverse reactions : Diarrhoea, Nausea, Headache, Vomiting, Rash			
Body as a whole : asthenia/fatigue, candidiasis, oedema/swelling, fever, pain, abdominal pain, chest pain;			
Cardiovascular System : extravasation, hypotension, bradycardia;			
Digestive System: acid regurgitation, anorexia, oral candidiasis, constipation, C.difficile-associated diarrhoea, dry mouth, dyspepsia;			
Nervous System & Psychiatric: confusion, dizziness, insomnia, somnolence;			
Respiratory System: dyspnoea			
Skin & Skin Appendage : erythema, pruritus;			
Special Senses: taste perversion;			
Urogenital System : vaginal pruritus.			
DOSAGE AND ADMINISTRATION :			
13 years of age and older			
The dose of Ertapenem in patients 13 years of age and older is 1 gram (g) given once a day			
3 months to 12 years of age			
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 for Injection may be administered by intravenous infusion for up to 14 days or intramuscular injection for up to 7 days. When administered intravenously, Ertapenem for Injection should be infused over a period of 30 minutes. Intramuscular administration of Ertapenem for Injection may be used as an alternative to intravenous administration in the treatment of those infections for which intramuscular therapy is appropriate.			
Table 1 presents treatment guidelines for Ertapenem.			
Table 1 Treatment Guidelines for Adults and Pediatric Patients With Normal Renal Function* and Body Weight			
Infection	Daily Dose (IV or IM) Adults and Patients 13 years of age and older	Daily Dose (IV or IM) Pediatric Patients 3 months to 12 years of age	Recommended Duration of Total Antimicrobial Treatment
Complicated intra-abdominal infections	1 g	15 mg/kg twice daily	5 to 14 days
Complicated skin and skin structure infections, including diabetic foot infections§	1 g	15 mg/kg twice daily	7 to 14 days¶
Community acquired pneumonia	1 g	15 mg/kg twice daily	10 to 14 days#
Complicated urinary tract infections, including pyelonephritis	1 g	15 mg/kg twice daily	10 to 14 days#
* defined as creatinine clearance > 90 mL/min/1.73 m2			
§ Ertapenem has not been studied in diabetic foot infections with concomitant osteomyelitis			

¶ adult patients with diabetic foot infections received up to 28 days of treatment (parenteral or parenteral plus oral switch therapy)		
# duration includes a possible switch to an appropriate oral therapy, after at least 3 days of parenteral therapy, once clinical improvement has been demonstrated.		
Prophylactic Regimen in Adults		
Table 2 presents prophylaxis guidelines for Ertapenem.		
Table 2 Prophylaxis Guidelines for Adults		
Indication	Daily Dose (IV) Adults	Recommended Duration of Total Antimicrobial Treatment
Prophylaxis of surgical	1 g	Single intravenous dose given
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 ≤30 mL/min/1.73 m2), including those on haemodialysis, should receive 500 mg daily. There are no data in paediatric patients with renal insufficiency.		
Patients on Haemodialysis: In a clinical study in adults, following a single 1 g IV dose of Ertapenem given immediately prior to a haemodialysis session, approximately 30% of the dose was recovered in the dialysate. When patients on haemodialysis are given the recommended daily dose of 500 mg of Ertapenem within 6 hours prior to haemodialysis, a supplementary dose of 150mg is recommended following the haemodialysis session. If Ertapenem is given at least 6 hours prior to haemodialysis, no supplementary dose is needed. There are no data in paediatric patients undergoing haemodialysis. There are no data in adult and paediatric patients undergoing peritoneal dialysis or haemofiltration.		
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 (micromol/L)		
Females: (0.85) x (value calculated for males)		
No dosage adjustment is recommended in patients with impaired hepatic function		
INSTRUCTIONS FOR USE		
Patients 13 years of age and older		
Preparation for intravenous administration:		
DO NOT MIX OR CO-INFUSE Ertapenem WITH OTHER MEDICATIONS.		
DO NOT USE DILUENTS CONTAINING DEXTROSE (α-D-GLUCOSE). α		
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 Injections, 0.9% Sodium Chloride Injection or Bacteriostatic Water for Injections.		
2. Shake well to dissolve and immediately transfer the contents of the reconstituted vial to 50 mL of 0.9% Sodium Chloride Injection. The resulting solution is chemically and physically stable only if used within 6 hours at room temperature, or stored for 24 hours at 2 to 8° C and used within 4 hours after removal from refrigeration.		
3. To ensure adequate potency and to avoid microbiological hazard, the Ertapenem solution should be used as soon as practicable after reconstitution and further dilution. If storage is unavoidable, the solution should be held at 2 to 8° C for not more than 24 hours, and used as soon as practicable within 4 hours after removal from refrigeration. The Ertapenem solution should not be frozen.		
4. Ertapenem should be infused over a period of 30 minutes.		
<u>Preparation for intramuscular administration:</u>		
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% lignocaine HCl injection*** (without adrenaline). Shake vial thoroughly to form solution. This solution is chemically and physically stable for only 1 hour at 2 to 8° C.		
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. To ensure adequate potency and to avoid microbiological hazard, the reconstituted solution should be used immediately or stored at 2 to 8° C for not more than 1 hour. Note: This reconstituted solution is for intramuscular administration only. It must not be administered intravenously.		
<u>Paediatric patients 3 months to 12 years of age</u>		
<u>Preparation for intravenous administration:</u>		
DO NOT MIX OR CO-INFUSE Ertapenem WITH OTHER MEDICATIONS.		
DO NOT USE DILUENTS CONTAINING DEXTROSE (α-D-GLUCOSE).		
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 Injections, 0.9% Sodium Chloride Injection or Bacteriostatic Water for Injections.		
2. Shake well to dissolve and immediately withdraw a volume equal to 15 mg/kg of body weight (not to exceed 1g/day) and dilute in 0.9% Sodium Chloride Injection to a final concentration of 20 mg/mL or less. The resulting solution is chemically and physically stable only if used within 6 hours at room temperature, or stored for 24 hours at 2 to 8° C and used within 4 hours after removal from refrigeration.		
3. To ensure adequate potency and to avoid microbiological hazard, the Ertapenem solution should be used as soon as practicable after reconstitution and further dilution. If storage is unavoidable, the solution should be held at 2 to 8° C for not more than 24 hours, and used as soon as practicable within 4 hours after removal from refrigeration. The Ertapenem solution should not be frozen.		
4. Ertapenem should be infused over a period of 30 minutes.		
<u>Preparation for intramuscular administration:</u>		
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% lignocaine HCl injection*** (without adrenaline). Shake vial thoroughly to form solution. This solution is chemically and physically stable for only 1 hour at 2 to 8° C.		
2. Immediately withdraw a volume equal to 15 mg/kg of body weight (not to exceed 1g/day) and administer by deep intramuscular injection into a large muscle mass (such as the gluteal muscles or lateral part of the thigh).		
3. To ensure adequate potency and to avoid microbiological hazard, the reconstituted solution should be used immediately or stored at 2 to 8° C for not more than 1 hour. Note: This reconstituted solution is for intramuscular administration only. It must not be administered intravenously.		
<u>Parenteral drug products should be inspected visually for particulate matter and discoloration prior to use, whenever solution and container permit. Solutions of Ertapenem range from colourless to pale yellow. Variations of colour within this range do not affect the potency of the product.</u>		
<u>Product is for single use in one patient only. Discard any residue.</u>		
OVERDOSAGE		
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 paediatric 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 haemodialysis; however, no information is available on the use of haemodialysis to treat overdosage.		
STORAGE		
Do not store lyophilized powder above 25°C (77°F)		
Solutions of Ertapenem for Injection should not be frozen. Discard Unused Portion.		
Reconstituted and infusion solutions		
For storage instructions for the reconstituted injection, see "Instructions for Use" above.		
SHELF-LIFE		
Shelf-life 24 months		
PRESENTATION :		
Ertapenem for Injection is supplied in 20 ml vials as Sterile, white to off white Lyophilized cake or powder for intravenous infusion or Intramuscular containing, Ertapenem Sodium eq. to 1gm Ertapenem.		
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