ERNEM™ 1g

(Ertapenem Sodium)
Injection

POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION

اَرنم ۱گرام
(ایرٹاپینم سوڈیم) انجیکشن
صرف وریدی استعمال کے لئے۔

Composition:
Each vial contains:
Ertapenem Sodium eq. to Ertapenem.....1g
Genix Specs.

INDICATIONS AND USAGE:
ERNEM is a carbapenem antibacterial indicated in adult patients and pediatric patients (3 months of age and older) for the treatment of the following moderate to severe infections caused by susceptible bacteria:
• 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 endometritis, septic abortion and post-surgical Gynecologic infections. ERNEM is indicated in adults for the prophylaxis of surgical site infection following elective colorectal surgery.

PHARMACOKINETICS:
Average plasma concentrations (mcg/mL) of Ertapenem following a single 30-minute infusion of a 1 g intravenous (IV) dose and administration of a single 1 g intramuscular (IM) dose in healthy young adults .The area under the plasma concentration-time curve (AUC) of ERNEM in adults increased less-than dose-proportional based on total Ertapenem concentrations over the 0.5 to 2 g dose range, whereas the AUC increased greater-than dose-proportional based on unbound Ertapenem concentrations.

ERNEM:
Exhibits non-linear pharmacokinetics due to concentration dependent plasma protein binding at the proposed therapeutic dose. There is no accumulation of ERNEM following multiple IV or IM 1 g daily doses in healthy adults.

DOSAGE AND ADMINISTRATION:
Do not mix or co-infuse ERNEM with other medications. Do not use diluents containing Dextrose (α–D–glucose). ERNEM should be infused over 30 minutes in both the Treatment and Prophylactic regimens.
Dosing considerations should be made in adults with advanced or end stage renal impairment and those on hemodialysis.
Treatment regimen:
• Adults and pediatric 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 15 mg/kg twice daily (not to exceed 1g/day intravenously or intramuscularly.)
• Intravenous infusion may be administered in adults and pediatrics for up to 14 days or intramuscular injection for up to 7 days.
Prophylaxis regimen for adults:
• 1 gram single dose given 1 hour prior to elective colorectal surgery.

WARNINGS AND PRECAUTIONS:
• Serious hypersensitivity (anaphylactic) reactions have been reported in patients receiving β-lactams.
• Seizures and other central nervous system adverse experiences have been reported during treatment.
• Co-administration of ERNEM with valproic acid or divalproex sodium reduces the serum concentration of valproic acid potentially increasing the risk of breakthrough seizures.
• Caution should be taken when administering ERNEM
Intramuscularly to avoid inadvertent injection into a blood vessel. 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 diagnose is patients who present with diarrhea subsequent to the administration of antibacterial agents. Studies indicated that a toxin produces by Clostridium difficile is a primary cause of "antibiotic associated colitis".

ADVERSE REACTIONS:
Adults: The most common adverse reactions (≥5%) in patients treated with ERNEM, including those who were switched to therapy with an oral Antimicrobial, were diarrhea, nausea, and headache and infused vein Complication. In the prophylaxis indication the overall adverse experience profile was generally comparable to that observed for ERNEM in other clinical trials.
Pediatrics: Adverse reactions in this population were comparable to adults. The most common adverse reactions (≥5%) in pediatric patients treated with ERNEM, including those who were switched to therapy with an oral antimicrobial, were diarrhea, vomiting and infusion site pain.

DRUG INTERACTIONS:
• Co-administration with probenecid inhibits the renal excretion of ERNEM and is therefore not recommended.
• The concomitant use of ERNEM 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.

USE IN SPECIFIC POPULATIONS:
Pediatric Use: Not Recommended in infants under 3 months of age.
Pregnancy: Catogery B
No well controlled trial in pregnant women.
Patients with Renal Impairment:
ERNEM may be used for the treatment of infections in

adult patients with renal impairment. In patients whose creatinine clearance is >30 mL/min/1.73m^2, no dosage adjustment is necessary. Adult patients with severe renal impairment (creatinine clearance ≤30 mL/min/1.73m^2 and end-stage renal disease (creatinine clearance ≤10 mL/min/1.73m^2 should receive 500 mg daily.

Patients on Hemodialysis:

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

Patients with Hepatic Impairment:

No dose adjustment recommendations can be made in patients with hepatic impairment.

PREPARATION AND RECONSTITUTION FOR ADMINISTRATION

Preparation for intravenous administration: Ernem must be reconstituted and then diluted prior to administration.

Pediatric patients 3 months to 12 years of age:

1. Reconstitute the contents of a 1 g vial of **ERNEM** 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.

Adults and paediatric patients 13 years of age and older:

1.Reconstitute the contents of a 1 g vial of ERNEM 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:

Ernem must be reconstituted prior to administration. Note: the reconstituted solution should not be administered intravenously in paediatric patients 3 months to 12 years of age.

1.Reconstitute the contents of a 1g vial of ERNEM with 3.2 mL of 1.0% 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.

Adults and paediatric patients 13 years of age and older:

1.Reconstitute the contents of a 1g vial of ERNEM with 3.2 mL of 1.0% 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.

CONTRAINDICATIONS:

• ERNEM is contraindicated in patients with known hypersensi- tivity 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, ERNEM administered intramuscularly is contraindicated in patients with a known hypersensitivity to local anesthetics of the amide type.

INSTRUCTIONS:

Before Reconstitution: Store below 25°C.
Protect from heat, light & moisture.

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 Ernem should not be frozen.Do not use, if injection contains undissolved particles. Use immediately after reconstitution. Keep all medicines out of the reach of children.

PRESENTATION:

ERNEM (Ertapenem Sodium) Injection 1g is available in pack of 1 Vial.

علامات/طریقہ استعمال:

بالغان میں انجکیو کولور یکلس سرجری کے بعد سرجری کی جگہ کو انفیکشن سے بچانے کے لئے احتیاطی طور پر دیا جاتا ہے۔

مضر اثرات: بالغان میں دست، متلی، سر درد اور دوران نفوذ وریدی پیچیدگی اور بچوں میں دست، اُلٹی اور جائے نفوذ پہ درد ہو سکتا ہے۔

احتیاطی تدابیر: حساسیت، دماغی دورے اور اعصابی نظام سے متعلق امراض ہونے کا خدشہ ہے۔

ہدایات: خوراک ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

۲۵ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ روشنی، گرمی اور نمی سے محفوظ رکھیں۔

0.9 فیصد سوڈیم کلورائیڈ کے ساتھ بنایا ہوا محلول ۶ گھنٹے کے لئے ۲۵ ڈگری سینٹی گریڈ پر محفوظ رہتا ہے اور ۴ گھنٹے کے لئے ۵ ڈگری سینٹی گریڈ پر ریفریجریٹر میں محفوظ کیا جا سکتا ہے۔ ریفریجریٹر سے نکالنے کے بعد ۴ گھنٹے کے اندر استعمال کریں۔ محلول کو منجمد نہ ہونے دیں۔

تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔ محلول میں کوئی غیر حل پذیر شے نظر آنے کی صورت میں ہرگز استعمال نہ کریں۔ تیار شدہ محلول فوری استعمال کر لیں۔

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