For the use of a Registered Medical Practioner or a Hospital or a Laboratory or only.

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Imipenem and Cilastatin Injection IP

AMERICAN

IMSTATIN 500 Injection

For IV Infusion Use Only

Composition :

Each vial contains :

Imipenem (Sterile)	IP
Eq. to Anhydrous Imipenem	500 mg
Cilastatin Sodium (Sterile)	IP
Eq. to Cilastatin	500 mg

(Sodium Bicarbonate IP added as buffer)

Dose Form: Powder for IV infusion only

DESCRIPTION ; **Imipenem/cilastatin** injection is an antibiotic useful for the treatment of a number of bacterial infections. It is a broad-spectrum beta-lactam containing equal quantities of imipenem and cilastatin. It is classified as belonging to the carbapenem class.

Pharmacology

Mechanism of action

Imipenem inhibits bacterial cell-wall synthesis by binding to penicillin-binding proteins; cilastatin prevents renal metabolism of imipenem.

Absorption

Bioavailability (IM): imipenem, 60–75%; cilastatin, 95–100%

Distribution

The drug is distributed rapidly and widely to most tissues and fluids, including sputum, pleural fluid, peritoneal fluid, interstitial fluid, bile, aqueous humor, reproductive organs, and bone; highest concentrations occur in pleural fluid, interstitial fluid, peritoneal fluid, and reproductive organs; low concentrations occur in CSF; it crosses the placenta, and enters breast milk

Protein binding

Imipenem, 13–21%; cilastatin, 40%

Metabolism

Imipenem is metabolized in the kidney by dehydropeptidase 1; activity is blocked by cilastatin.

Elimination

Half-life (both drugs): 60 min; prolonged with renal impairment Excretion (both drugs): Urine (~70% as unchanged drug)

Pharmacokinetics

Mechanism of action

Imipenem/cilastatin has the ability to kill a wide variety of bacteria. Imipenem is the active antibiotic agent and works by interfering with their ability to form cell walls, so the bacteria break up and die.Imipenem is rapidly degraded by the renal enzyme dehydropeptidase if administered alone (making it less effective); the metabolites can cause kidney damage. Imipenem is a broad-spectrum betalactam antibiotic used for severe bacterial infections caused by susceptible organisms. Because imipenem is rapidly inactivated by renal dehydropeptidase I, it is given in combination with cilastatin, a DHP-I inhibitor which increases half-life and tissue penetration of imipenem. Imipenem/cilastatin, like other carbapenems, binds to bacterial penicillin-binding proteins and interferes with bacterial cell wall integrity and synthesis.

Microbiology :

It has activity against many aerobic and anaerobic Gram-positive and Gram-negative organisms, including *Staphylococcus aureus, Streptococcus pyogenes, S. agalactiae, S. viridans*- group streptococci, *Enterococcus faecalis, Pseudomonas aeruginosa, Escherichia coli, Proteus mirabilis, Bacteroides fragilis* and *Peptostreptococcus* species

Indication: Imipenem/cilastatin is indicated for the treatment of severe or complicated skin, tissue, joint, respiratory tract, intra-abdominal, urinary tract and urogenital infections, but not meningitis (as it does not pass through the blood brain barrier), endocarditis, and sepsis due to susceptible organisms. Its use is generally restricted to severe infections largely in hospitalized patients

DIRECTIONS FOR ADMINISTRATION.

Disperse the contents of each 500-mg vial in 10ml water for Injection or NaCl 0.9% to produce a suspension of the drug.

2. Withdraw the required dose from the vial(s) and add to 100ml NaCl 0.9%. If necessary, use a further 10ml NaCl 0.9% to effectively 'wash out' the vial (s) and add this to the infusion bag to ensure complete transfer of vial contents.

3. Agitate the bag to ensure complete mixing.

4. The solution should be clear and colourless to yellow. Inspect visually for particulate matter or discoloration prior to administration and discard if present.

5. Give by IV infusion. Give 250-500mg over 20-30 minutes and 1 g over 40-60 minutes. The infusion rate should be slowed if the patient develops nausea during the infusion.

DOSE ADMINSTRATION : The recommended dosage is 250 mg to 1 gram given intravenously every 6 to 8 hours or in intramuscular doses of no more than 1.5 gm daily, usually for five to 14 days.

Side Effect : The most common side effects are diarrhea, stomach pain, nausea, vomiting, skin rash, pruritus, fever,facial swelling difficulty breathing, unusual bleeding and injection-site reactions.

Contraindications

Hypersensitivity to imipenem or cilastatin

Warning & Precaution

- History of hypersensitivity to penicillins
- Use with caution in CNS disorders (eg., history of seizures); adjust dosage in renal impairment to avoid risk of seizures; carbapenem use has been associated with seizures
- Prolonged use increases risk of superinfections
- Use with caution in renal impairment; adjust dosage in moderate to severe renal dysfunction
- Carbapenem use may decrease serum levels of divalproex sodium or valproic acid
- Combination with aminoglycosides may thwart resistant P aeruginosa
- Not for use in children with CNS problems

Pregnancy & Lactation

Pregnancy category: C

Lactation: Drug distributed in breast milk; use with caution

Overdose

If overdose is suspected, contact a poison control center or emergency room immediately.. Symptoms of overdose may include: seizures.

Storage Condition : Store below 25°C. Protect from light & moisture.

Improper storage may deteriorate the product.

Presentation : Imipenem & Cilastatin Injection IP is white dry powder filled in clear glass vial. with SWFI

Manufactured by:

AMERICAN REMEDIES © Care & Cure with Research

American Remedies Healthcare Pvt. Ltd.

(An ISO 9001-2015 Certified Company)

ICO: American Remedies LLC, DE, USA

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