

LASNEM[®]
For Intravenous
Infusion
(Imipenem and Cilastatin)
Powder For Injection U.S.P.

500mg / 500mg



DESCRIPTION: Lasnem (Imipenem and Cilastatin Sodium) is a broad spectrum beta-lactam antibiotic supplied as intravenous infusion only. Lasnem consists of two components: Imipenem and Cilastatin Sodium which are present in Lasnem in a 1:1 ratio by weight.

COMPOSITION:

Lasnem® 500mg/500mg: Each vial contains:
Imipenem (as Monohydrate).....500mg
Cilastatin Sodium eq. to Cilastatin.....500mg
Sterile mixture also contains Sodium Bicarbonate as buffer. The Sodium content is approx. 37.5mg (1.6mEq.)

MICROBIOLOGY: Lasnem I.V. is a potent inhibitor of bacterial cell-wall synthesis and is bactericidal against a broad spectrum of pathogens- gram-positive and gram-negative, aerobic and anaerobic.

INDICATION: Lasnem is indicated for the treatment of the following infections due to susceptible organisms: • Intra-abdominal infections • Lower respiratory tract infections • Gynecological infections • Septicemia • Genitourinary tract infections • Bone and joint infections • Skin and soft tissue infections • Endocarditis. Lasnem is indicated for the treatment of mixed infections caused by susceptible strains of aerobic and anaerobic bacteria. Lasnem is not indicated for the treatment of meningitis.

PROPHYLAXIS: Lasnem is also indicated for the prevention of certain post-operative infections in patients undergoing contaminated or potentially contaminated surgical procedures or where the occurrence of post-operative infection could be especially serious.

DOSAGE AND ADMINISTRATION: Lasnem is available as intravenous infusion only. The dosage recommendations for Lasnem represent the quantity of imipenem to be administered. An equivalent amount of cilastatin is also present. The total daily dosage of Lasnem should be based on the type or severity of infection and given in equally divided doses based on consideration of degree of susceptibility of the pathogen, renal function and body weight.

INTRAVENOUS INFUSION: Treatment: Adult Dosage Schedule For Patients With Normal Renal Function: Most infections respond to a daily dose of 1-2 g administered in 3-4 divided doses. For the treatment of moderate infection, a 1g b.i.d. dosage regimen may also be used. In infections due to less susceptible organisms, the daily dosage of Lasnem I.V. may be increased to a maximum of 4

g/day or 50 mg/kg/day, whichever is lower. Each dose of ≤500mg / 500mg of Lasnem I.V. should be given by intravenous infusion over 20 to 30 minutes. Each dose > 500 mg should be infused over 40 to 60 minutes. In patients who develop nausea during the infusion, the rate of infusion may be slowed.

I.V. Dosage schedule for adults with normal renal function and body weight 70 kg*

SEVERITY OF INFECTION	DOSE (mg of Imipenem/ Cilastatin)	DOSAGE INTERVAL	TOTAL DAILY DOSAGE
Mild	250 mg	6 hrs	1g
Moderate	500 mg	8 hrs	1.5g
	1000 mg	12 hrs	2g
Severe - Fully susceptible	500 mg	6 hrs	2g
Severe and/or Life-threatening - Due to less susceptible organisms (primarily some strains of P. aeruginosa)	1000 mg	8 hrs	3g
	1000 mg	6 hrs	4g

*A further proportionate reduction in dose administered must be made for patients with a body weight < 70 kg. Due to high antimicrobial activity of Lasnem™, it is recommended that the maximum total daily dosage not exceed 50 mg/kg/day or 4 g/day.

TREATMENT: ADULT DOSAGE SCHEDULE FOR PATIENTS WITH IMPAIRED RENAL FUNCTION: To determine the reduced dose for adults with impaired renal function.

PROPHYLAXIS: ADULT DOSAGE SCHEDULE: For prophylaxis against post-surgical infections in adults, 1000mg/1000mg Lasnem I.V. should be given intravenously on induction of anesthesia and 1000mg/1000mg three hours later. For high-risk (e.g. colorectal) surgery, two additional 500mg/500mg doses can be given at eight and sixteen hours after induction.

TREATMENT: PEDIATRIC DOSAGE SCHEDULE (3 months or older) For children and infants the following dosage schedule is recommended: (a) Children 40 kg body weight should receive adult doses. (b) Children AND INFANTS < 40 kg body weight should receive 15 mg/kg at six hour intervals. The total daily dose should not exceed 2 gm. Clinical data are insufficient to recommend dosing for children less than 3 months of age, or pediatric patients with impaired renal function (serum creatinine > 2 mg/dL). Lasnem is not recommended for the therapy of meningitis. If meningitis is suspected, an appropriate antibiotic should be used.

RECONSTITUTION, INTRAVENOUS SOLUTION: Lasnem I.V for intravenous infusion is supplied as a sterile powder in vial of containing 500mg imipenem equivalent and 500mg cilastatin equivalent. Lasnem I.V. is buffered with Sodium Bicarbonate to provide solutions in the pH range of 6.5 to 8.5. There is no significant change in pH when solutions are prepared and used as directed. Sterile powder Lasnem I.V. should be reconstituted as shown in Table. It should be shaken until a clear solution is obtained. Variations of color, from colorless to yellow, do not affect the potency of the product.

Reconstitution of Lasnem I.V.

Dose of Lasnem I.V. (mg of Impipenem/ Cilastatin)	Volume of Diluent To Be Added (ml)	Approx. Average Concentration of Lasnem I.V. (mg/ml of Impipenem/Cilastatin)
500mg/500mg	100	5

Reconstitution of 500mg/500mg of the vials must be suspended & transferred to 100mL. A suggested procedure is to add approximately 10 mL from the appropriate infusion solution (see the STABILITY, Lasnem I.V.) to the vial. Shake well and transfer the resulting suspension to the infusion solution container. Repeat with an additional 10 mL of infusion solution to ensure complete transfer of vial contents to the infusion solution. The resulting mixture should be agitated until clear.

CAUTION: THE SUSPENSION IS NOT FOR DIRECT INFUSION:

STABILITY, Lasnem I.V.: Store the dry powder at room temperature (Below 25°C). Table shows the stability period for Lasnem I.V. when reconstituted with selected infusion solutions, and stored at room temperature or under refrigeration.

CAUTION: Lasnem I.V. is chemically incompatible with lactate and should not be reconstituted in diluents containing lactate. Lasnem I.V. can be administered, however, into an I.V. system through which a lactate solution is being infused. Lasnem I.V. should not be mixed with or physically added to other antibiotics.

Stability of Reconstituted of Lasnem I.V.

Diluent	Stability Period	
	Room Temperature (25°C)	Refrigeration (5°C)
Isotonic Sodium Chloride	4 hrs	24 hrs
5% Dextrose in Water	4 hrs	24 hrs
10% Dextrose in Water	4 hrs	24 hrs
5% Dextrose & 0.9% NaCl	4 hrs	24 hrs
5% Dextrose & 0.45% NaCl	4 hrs	24 hrs
5% Dextrose & 0.225% NaCl	4 hrs	24 hrs
5% Dextrose & 0.15% KCl	4 hrs	24 hrs
Mannitol 5% and 10%	4 hrs	24 hrs

DRUG-INTERACTION: Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Tell your doctor if you are taking ganciclovir which is used to treat some viral infections. Also, tell your doctor if you are taking Valproic acid or Sodium Valproate (used to treat epilepsy, bipolar disorder, migraine, or schizophrenia) or any blood thinners such as warfarin. Your doctor will decide whether you should use Lasnem I.V. in combination with these medicines.

USE IN PREGNANCY: There are no adequate and well-controlled studies in pregnant women. Lasnem I.V. should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

NURSING MOTHERS: Impipenem has been detected in human milk. If the use of Lasnem is deemed essential, the patient should stop nursing.

POSSIBLE SIDE EFFECTS: Common: Nausea, vomiting, diarrhoea. Nausea and vomiting appear to occur more frequently in patients with low number of white blood cells, Swelling and redness along a vein which is extremely tender when touched, Rash, Abnormal liver function detected by blood tests • Increase in some white blood cells

WHAT LASNEM I.V LOOKS LIKE AND CONTENTS OF THE PACK: Lasnem I.V is a white to light yellow powder for solution for infusion in a glass vial. Pack sizes of 1 vials. Each vial is for single use only.

DOSSAGE: As directed by the physician.

INSTRUCTIONS: Store below 25°C. Protect from heat, light & moisture. After constitution it is to be solubilized in a suitable parenteral fluid prior to intravenous infusion. Keep all medicines out of the reach of children.

PRESENTATION:

Lasnem (Impipenem / Cilastatin) for Injection U.S.P. 500mg/500mg is available in pack of 1 Vial.

سولژن بنائے کا طریقہ:

سولژن بنانے کے لئے 100 ملی لیٹر کنٹینر میں 500mg/500mg سے وائل میں ڈالیں۔
اچھی طرح ہلائیں اور بنائے ہوئے اسپینش کو انفیوژن میں واپس شامل کریں۔

نوٹ: ڈاؤن لوڈ کی ہدایت کے مطابق استعمال کریں۔

ہدایت: 25°C ذریعہ برقی بریڈ سے کم درجہ حرارت پر رکھیں۔ روشنی اور نمی سے محفوظ رکھیں۔

اسپینش کو براہ راست استعمال نہ کریں۔ تمام دوائیوں کی پٹیج سے دور رکھیں۔

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ISO 9001:2015

ISO 14001:2015

ISO 45001:2018

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