R-penem™

Meropenem

Composition:
R-penem™ 500 IV Injection: Each vial contains sterile Meropenem USP 500 mg.
R-penem™ 1 g IV Injection: Each vial contains sterile Meropenem USP 1 g.

Description:
R-penem™ (Meropenem) is a sterile, pyrogen-free, synthetic, broad-spectrum, carbapenem antibiotic for intravenous administration that exerts its bactericidal action by interfering with bacterial cell wall synthesis. It penetrates into bacterial cell walls with its high level of stability to all betalactamases and marked affinity for the Penicillin Binding Proteins (PBPs). The in vitro antibacterial spectrum of Meropenem includes the majority of clinically significant Gram-positive and Gram-negative, aerobic and anaerobic strains of bacteria.

Indications:
R-penem™ is indicated for the treatment of:
- Pneumonias and Nosocomial Pneumonias
- Urinary Tract Infections
- Intra-abdominal Infections
- Gynecological Infections such as endometritis
- Skin and Skin Structure Infections
- Meningitis
- Septicaemia
- Empiric treatment for presumed infections in adult patients with Febrile neutropenia
- Other polymicrobial infections

R-penem™ is only suitable for symptomatic therapy. Benzodiazepine should only be used if the disease is difficult, the patient is greatly hindered or extremely suffering.

Dosage & Administration:
Adult: The dosage and duration of therapy shall be established depending on type and severity of infection and the condition of the patient.
The recommended daily dosage is as follows:-
In the treatment of pneumonia, UTI, gynecological infections such as endometritis, skin and skin structure infections- 500 mg IV every 8 hours.
In the treatment of nosocomial pneumonias, peritonitis, presumed infections in neutropenic patients, septicaemia- 1 g IV every 8 hours.
In cystic fibrosis- doses up to 2 g every 8 hours
In meningitis- 2 g every 8 hours.
As with other antibiotics, particular caution is recommended in using meropenem as monotherapy in critically ill patients with known or suspected *Pseudomonas aeruginosa* lower respiratory tract infection.
Regular sensitivity testing is recommended when treating *Pseudomonas aeruginosa* infection.

Patients with Impaired Renal Function:

Creatinine clearance (mL/min)	Dose (Depending on types of infections)	Dosing Interval
>50	Recommended Dose	Every 8 hours
>25-50	Recommended Dose	Every 12 hours
10-25	One half of recommended dose	Every 12 hours
<10	One half of recommended dose	Every 24 hours

Children (≥3 months):
Over 3 months to 12 years- 10 to 20 mg/kg every 8 hours.
Children over 50 kg weight- adult dosage should be used.
4 years to 18 years with cystic fibrosis- 25 to 40 mg/kg every 8 hours.
In meningitis- 40 mg/kg every 8 hours.
There is no experience in children with altered hepatic or renal function.
Patients with Hepatic Insufficiency: No dosage adjustment is necessary in patients with hepatic insufficiency.
Elderly Patients: No dosage adjustment is required for the elderly with normal renal function or creatinine clearance values above 50 ml/min.
OR AS DIRECTED BY THE PHYSICIAN.

Reconstitution Procedure:
Constitute injection vials of R-penem 500 & R-penem 1 g with adding 10 ml & 20 ml sterile water for injection into vials respectively. Shake to dissolve & let stand clear.

Side Effects:
Swelling, redness, pain, or soreness at the injection site may occur. This medication may also infrequently cause upset stomach, headache, nausea, vomiting, constipation, or diarrhea.

Precautions:
Prescribing Meropenem 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. Seizures and other adverse CNS experiences have been reported during treatment with Meropenem.
Pregnancy: Pregnancy Category B.
Lactation: Meropenem has not been detected in breast milk though caution is recommended.

Contraindications:
Meropenem is contraindicated in patients with known hypersensitivity to it.

Drug Interaction:
Some products that may interact with this drug include: live bacterial vaccines, probenecid, valproic acid, other antibiotics.

Storage Condition:
Prior to constitution, store Meropenem powder for intravenous injection or infusion packs below 25 °C. To reduce microbiological hazard, solutions of Meropenem IV should be used as soon as practicable after reconstitution. If storage is necessary, hold at 2 to 8 °C for not more than 24 hours. Solutions of Meropenem should not be frozen. Keep out of the reach of children.

Packaging:
R-penem™ 500 IV Injection: Each box contains one combipack and a 10 ml sterile disposable syringe. The combipack contains one vial of Meropenem 500 mg & one ampoule of 10 ml Water for Injection BP.

R-penem™ 1 g IV Injection: Each box contains one combipack and a 20 ml sterile disposable syringe. The combipack contains one vial of Meropenem 1 g & two ampoules of 10 ml Water for Injection BP.

Manufactured by:
Julphar Bangladesh Ltd.
Sreepur, Gazipur, Bangladesh.