Ronem® *250 Injection*

Meropenem

Description

Meropenem (**Ronem**®) is a broad spectrum ß-lactam antibacterial agent of the carbapenem class. Like other ß-lactam antibiotic, it is bactericidal in action exerting its effect by inhibiting transpeptidase enzyme responsible for cell-wall synthesis. It has a very broad spectrum of activity, including activity against Gram-positive and Gram-negative aerobic and anaerobic organisms, and is stable to hydrolysis by beta-lactamases enzyme produced by most bacterial species. Meropenem is more stable to renal dehydropeptidase-I than Imipenem/Cilastatin.

Mode of action

Meropenem (**Ronem**®) inhibits bacterial cell wall synthesis and thus exerts bactericidal action.

Pharmacokinetics

Following intravenous injection of Meropenem 250 mg, 500 mg and 1g over 5 minutes, peak plasma concentrations of about 50 and 112 μg/ml respectively are attained. The same doses infused over 30 minutes produce peak plasma concentrations of about 23 and 49 μg/ml, respectively. Meropenem has a plasma elimination half-life of about 1 hour; this may be prolonged in patients with renal impairment and is also slightly prolonged in children. Meropenem is widely distributed into body tissues and fluids including the CSF and bile. It is more stable to renal dehydropeptidase-I than Imipenem and mainly excreted by urine, by tubular secretion and glomerular filtration. About 70% of a dose is recovered unchanged in the urine over a 12-hour period and urinary concentrations above 10 μg/ml are maintained for upto 5 hours after a 500 mg dose. Meropenem has one reactive metabolite which is excreted in the urine. Meropenem is removed by haemodialysis.

Composition

Ronem® 250 mg Injection: Each vial contains sterile dry mixture of Meropenem and Sodium Carbonate USP 320.5 mg equivalent to Meropenem 250 mg.

Indications

Ronem® is indicated for the treatment of following indications caused by single or multiple bacteria sensitive to Meropenem and as empiric therapy prior to the identification of causative organisms. Intra-abdominal sepsis, deep gynecological and obstetric infections, septicemia of unknown etiology, meningitis, pulmonary infections in cystic fibrosis patients, febrile neutropenia, pneumonia, urinary tract infections, and skin and skin structure infections.

Dosage and administration

Paediatric Patients: For paediatric patients from 3 months to 12 years of age, Meropenem dose is 20 or 40 mg/kg every 8 hours (maximum dose is 2g every 8 hours), depending on the type of infection (intra-abdominal or meningitis). Paediatric patients weighing over 50 kg should be administered Meropenem at a dose of 1 g every 8 hours for intra-abdominal infections and 2g every 8 hours for meningitis.

Recommended Dosage Schedule for Paediatric Patients with Normal Renal Function:

Type of infection	Dose (mg/kg)	Dosing interval
Intra-abdominal infection	20	Every 8 hours
Meningitis	40	Every 8 hours

Adults: The dosage and duration of therapy shall be established depending on type and severity of infection and the condition of the patient. Usual adult dose is 500 mg to 1g by intravenous administration every 8 hours. Meropenem should be given by intravenous infusion, over approximately 15 to 30 minutes or as an intravenous bolus injection (5 to 20 mL) over approximately 3-5 minutes.

Indication wise recommended daily dosage is as follows:

- 500 mg IV every 8 hours in the treatment of pneumonia, UTI, gynecological infection such as endometritis, skin and skin structure infections.
- 1 g IV every 8 hours in the treatment of nosocomial pneumonia, peritonitis, presumed infection in neutropenic patients, septicemia.
- In meningitis the recommended daily dosage is 2 g every 8 hours.

Dosage schedule for Adults with Renal Impairment: Dosage should be reduced in patients with creatinine clearance less than 51 mL/min.

Recommended Dosage Schedule:

Creatinine clearance (mL/min)	Dose (dependent on type of infection)	Dosing interval
26-50	Recommended dose	Every 12 hours
10-25	One-half of recommended dose	Every 12 hours
<10	One-half of recommended dose	Every 24 hours

Dosage for Adults with Hepatic Insufficiency: No dosage adjustment is necessary in patients with impaired hepatic function.

Dosage for Elderly Patients: No dosage adjustment is required for elderly patients with creatinine clearance greater than 50 ml/min.

Instruction for use

For Intravenous bolus administration, constitute injection vials (500 mg and 1 g) with sterile Water for Injection. Shake to dissolve and let stand until clear. Freshly constituted solutions are clear, and colorless or pale yellow.

Strength	Amount of diluent to be added (mL)	Approximate withdrawable volume (mL)	Approximate withdrawable concentration (mg/mL)
250 mg	5	5	50
500 mg	10	10	50
1 g	20	20	50

Infusion vial (1 g injection) may be directly constituted with a compatible infusion fluid. Alternatively, an injection vial may be constituted, then the