

ROPENEM

Meropenem Trihydrate USP 250mg, 500mg & 1gm Injection

Composition : **Ropenem-250** Injection (IV) : Each vial contains Meropenem 250mg as Meropenem Trihydrate USP sterile powder.

Ropenem-500 Injection (IV) : Each vial contains Meropenem 500mg as Meropenem Trihydrate USP sterile powder.

Ropenem-1gm Injection (IV) : Each vial contains Meropenem 1gm as Meropenem Trihydrate USP sterile powder.

Pharmacology : Meropenem is an antibacterial drug. The plasma protein binding of meropenem is approximately 2%. In subjects with normal renal function, the elimination half-life of meropenem is approximately 1 hour. Meropenem is primarily excreted unchanged by the kidneys.

Indications : Meropenem IV is indicated for the treatment, in adults and children, of the following infections caused by single or multiple bacteria sensitive to Meropenem. These are as follows: Pneumonias and nosocomial pneumonias, Urinary tract infections, Intra-abdominal infections, Gynaecological Infections, such as endometritis skin and skin structure infections, Meningitis, Septicaemia, Empiric treatment, including monotherapy, for presumed infections in adult patient with febrile neutropenia.

Dosage and administration : Adults: The dosage and duration of therapy shall be established depending on type and severity of infection and condition of the patient. The recommended daily dosage is as follow: 500mg IV every 8 hours in the treatment of pneumonia, UTI, Gynaecological infections such as endometritis, skin and skin structure infections, 1g IV every 8 hours in the treatment of nosocomial pneumonias, peritonitis, presumed infections in neutropenic patients, septicemia. In cystic fibrosis, doses up to 2g every 8 hours have been used. In meningitis the recommended dosage is 2g every 8 hours.

Dosage Schedule for Adults with impaired renal function :

Creatinine Clearance (ml/min)	Dose (Based on unit doses of 500mg, 1g, 2g)	Frequency
26 to 50	one unit dose	every 12 hours
10 to 25	one-half unit dose	every 12 hours
<10	one-half unit dose	every 24 hours

Children: For children over 3 months and up to 12 years of age, the recommended dose is 10 to 40 mg/kg every 8 hours depending on type and severity of infection, susceptibility of the pathogen and the condition of the patient. In children over 50kg weight, adult dosage should be used.

Recommended Dosage Schedule for Pediatric Patients 3 months of age and older with normal renal function :

Type of Infection	Dose (mg/kg)	Up to a Maximum Dose	Dosing Interval
Complicated skin and skin structure infections	10	500mg	Every 8 hours
Complicated intra-abdominal infections	20	1 gram	Every 8 hours
Meningitis	40	2 grams	Every 8 hours

Or, as directed by the registered physician.

Method of Administration: Ropenem to be used for bolus intravenous injection should be constituted with sterile water for injection (5ml per 250mg meropenem). This provides an approximate available concentration of 50mg/ml. Constituted solutions are clear or pale yellow.

Contraindications : Meropenem is contraindicated in patients who have demonstrated hypersensitivity to this product.

Precautions : Use of Meropenem in patients with hepatic disease should be made with careful monitoring of transaminase and bilirubin levels.

Side effects : Serious adverse effects are rare. During the clinical trials the following adverse events have been reported: inflammation, thrombophlebitis, pain at the site of injection, rash, pruritus, urticaria, rarely severe skin reactions.

Use in Pregnancy and lactation : Pregnancy category B. No adequate & well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed. Since Meropenem is excreted in human milk, caution should be exercised when Meropenem is administered to nursing mother.

Use in Child : See dosage and administration.

Drug Interactions : The co-administration of Meropenem with probenecid is not recommended. Meropenem has been administered concomitantly with other medications without adverse pharmacological interactions.

Overdose : Symptoms of overdose include ataxia, dyspnea, convulsions and mortalities.

Storage : Store below 30°C in a dry place.

Packing : **Ropenem-250** Injection (IV) : Blister pack of 1 vial containing Meropenem 250mg (as Meropenem Trihydrate USP sterile powder) and one ampoule of 5ml water for injection BP as solvent.

Ropenem-500 Injection (IV) : Blister pack of 1 vial containing Meropenem 500mg (as Meropenem Trihydrate USP sterile powder) and one ampoule of 10ml water for injection BP as solvent.

Ropenem-1gm Injection (IV) : Blister pack of 1 vial containing Meropenem 1gm (as Meropenem Trihydrate USP sterile powder) and two ampoules of 10ml water for injection BP as solvent.

Manufactured by
DRUG INTERNATIONAL LTD.
Tongi, Gazipur, Bangladesh