MEROTRAX

MEROPENEM USP

Compositions:
Each vial contains Meropenem USP 500 mg as Meropenem Sodium Carbonate. Merotrax IV injection/Infusion: Each vial contains Meropenem USP 1g as Meropenem Sodium Carbonate.

Pharmacology:
Meropenem is a carbapenem antibiotic for parenteral use, that is relatively stable to human dehydropeptidase-1 (DHP-1) and therefore does not require the addition of an inhibitor of DHP-1. Meropenem exerts its bactericidal action by interfering with vital bacterial cell wall synthesis. The ease with which it penetrates bacterial cell walls, its high level of stability to all serine beta-lactamases and its marked affinity for the Penicillin Binding Proteins (PBPs) explain the potent bactericidal action of meropenem against a broad spectrum of aerobic and anaerobic bacteria.

Dosage And Administration:
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:- Adults: The adult dose is 1 gm by intravenous infusion over 15-30 minutes or as intravenous bolus (5 to 20 mL) over 3-5 minutes every 8 hours. Pneumonia, urinary tract infections, gynaecological infections such as endometritis, skin and skin structure infections: 500 mg IV every 8 hours. Nosocomial pneumonias, peritonitis, presumed infections in neutropenic patients and septicaemia: 1g IV every 8 hours. Intra-abdominal infections: 500 mg to 1 gm every 8 hours. Meningitis: 2 gm IV every 8 hours. Children: Children 3 months -12 years: 20 or 40 mg/kg intravenously every 8 hours depending on type and severity of infection, susceptibility of the pathogen(s) and the condition of the patient. Intra-abdominal infections: 20 mg/kg every 8 hours. Cystic fibrosis (4-18 years): 25-40 mg/kg every 8 hours. Meningitis: 40 mg/kg IV every 8 hours. Children over 50 kg weight: use adult dosage. There is no experience in children with hepatic or renal impairment. Renal impairment: No dosage adjustment is required for the elderly with normal renal function or creatinine clearance values above 50 ml/min. CrCl 26-50 mL/min, 1 gm every 12 hours; CrCl 10-25 mL/min, 500 mg every 12 hours; and CrCl

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

Warning And Precaution:
If an allergic reaction to Meropenem occurs, the drug should be discontinued and appropriate measures taken. Use of Meropenem in patients with hepatic disease should be made with careful monitoring of transaminase and bilirubin levels.

Side Effects:
Meropenem is generally well tolerated. Local injection site reactions, rash, pruritus, urticaria, abdominal pain, nausea, vomiting, diarrhoea, pseudomembranous colitis. Rarely erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis. Headache, paraesthesia and infrequently convulsions (although no causal relationship has been established). Oral and vaginal candidosis. Reversible thrombocythaemia, leucopenia, eosinophilia, thrombocytopenia and neutropenia (including rare cases of agranulocytosis). Positive Coombs test. Reduction in partial thromboplastin. Rarely systemic allergic reactions (hypersensitivity), which may include angioedema and manifestations of anaphylaxis.

Use in Pregnancy and Lactation:
Pregnancy: The safety of Meropenem in human pregnancy has not been evaluated. Meropenem should not be used in pregnancy unless the potential benefit justifies the potential risk to the foetus. In every case, it should be used under the direct supervision of the physician. Lactation: Meropenem is detectable at very low concentrations in animal breast milk. Meropenem should not be used in breast-feeding women unless the potential benefit justifies the potential risk to the baby.

Drug Interaction:
Probenecid competes with Meropenem for active tubular secretion and thus inhibits the renal excretion, with the effect of increasing the elimination half-life and plasma concentration of Meropenem. Meropenem may reduce serum valproic acid levels. Sub therapeutic levels may be reached in some patients.

Overdosage:
Accidental overdosage could occur during therapy, particularly in patients with renal impairment. Treatment of overdosage should be symptomatic. In normal individuals, rapid renal elimination will occur; in subjects with renal impairment, haemodialysis will remove Meropenem and its metabolite.

Storage:
Vial store in a cool, dry place (below 30oC), away from light & moisture. Keep out of the reach of children.

Packing:
Each pack contains 1 vial of Meropenem USP for Injection equivalent to Meropenem 500 mg, 1 ampoule of 10 ml of Water for Injection BP and a sterile disposable syringe (10 ml). Meropenem 1 gm IV Injection/ Infusion: Each pack contains 1 vial of Meropenem USP for Injection equivalent to Meropenem 1 gm, 2 ampoules of 10 ml of Water for Injection BP, one butterfly needle and a sterile disposable syringe (20 ml).

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.