# Mepen

Meropenem

**Composition**

**Mepen 500 mg IV Injection:** Each vial contains Sterile dry mixture of Meropenem and sodium carbonate USP equivalent to meropenem 500 mg.

**Mepen 1 gm IV Injection:** Each vial contains Sterile dry mixture of Meropenem and sodium carbonate USP equivalent to meropenem 1gm.

**Description**

Meropenem is a carbapenem antibiotic for parenteral use, that is stable to human dehydropeptidase-I (DHP-I). Meropenem exerts its bactericidal action by interfering with vital bacterial cell wall synthesis.

**Indications**

Mepen is indicated for treatment of :

Lower Respiratory Tract Infections
Urinary Tract Infections
Pneumonia
Febrile Neutropenia
Intra-abdominal Infections
Gynaecological Infections, including postpartum infections
Skin and Skin Structure Infections
Meningitis
Septicaemia

**Dosage and Administration**

**ADULTS:** Usual dose 500 mg to 1 gm by intravenous administration every 8 hours depending on type and severity of infection, the known or expected susceptibility of the pathogen(s) and the condition of the patient.

**ELDERLY:** No dosage adjustment is required for the elderly with normal renal function or creatinine clearance values above 50 ml/min.

**CHILDREN:** For infants and children over 3 months and up to 12 years of age the recommende intravenous dose is 10 to 40 mg/kg every 8 hours depending on type and severity of infection, the known or suspected susceptibility of the pathogen(s) and the condition of the patient. In children over 50 kg weight, adult dosage should be used.

Dosage should be reduced in patients with creatinine clearance less than 51 ml/min, as scheduled below.

| Creatinine Clearance (mL/min) | Dose (based on unit doses of 500 mg, 1 gm, 2 gm every 8 hours) | 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 |

Mepen is cleared by haemodialysis. If continued treatment with Mepen is necessary, the unit dose (based on the type and severity of infection) is recommended at the completion of the haemodialysis procedure to re-institute effective treatment.

**Use in Adults with Hepatic Insufficiency**

No dosage adjustment is necessary in patients with impaired hepatic metabolism.

**Method of Administration**

Mepen to be used for bolus intravenous injection should be constituted with sterile water for injection (10 ml per 500 mg Meropenem). This provides an approximate available concentration of 50 mg/ml. Constituted solutions are clear or pale yellow. Mepen for intravenous infusion may be directly constituted with a compatible infusion fluid and then further diluted (50 to 200 ml) with the compatible infusion fluid, as needed. Mepen IV is compatible with the following infusion fluids: 0.9% sodium chloride intravenous infusion, 5% or 10% glucose intravenous infusion, 5% glucose intravenous infusion with 0.02% sodium bicarbonate, 5% glucose and 0.9% sodium chloride intravenous infusion, 5% glucose with 0.225% sodium chloride intravenous infusion, 5%

glucose with 0.15% potassium chloride intravenous infusion, 2.5% and 10% mannitol intravenous infusion.

**Use in special group**

**Pregnancy:** Pregnancy category B. The safety of Mepen in human pregnancy has not been established, although animal studies have not shown an adverse effect on the developing foetus. Mepen should not be used in pregnancy unless the potential benefit justifies the potential risk to the foetus.

**Lactation:** Meropenem is detectable at very low concentrations in animal breast milk. Mepen should not be used in breast-feeding women unless the potential benefit justifies the potential risk to the baby.

**Use in Children:** Efficacy and tolerability in infants under 3 months old have not been established; therefore, Mepen is not recommended for use below this age.

**Side Effects**

Mepen is generally well tolerated. Adverse events rarely lead to cessation of treatment. Serious adverse events are rare thrombocythaemia, nausea, vomiting, diarrhea, increases in serum transaminases, bilirubin, alkaline phosphatase, lactic dehydrogenase, inflammation, thrombophlebitis, pain, eosinophilia, thrombocytopenia, headache, paresthesia, rash, urticaria, pruritus, leucopenia, neutropenia, agranulocytosis, convulsions, oral and vaginal candidiasis, haemolyticanaemia, angioedema, manifestations of anaphylaxis, pseudomembranous colitis, erythema multiforme, Stevens Johnson syndrome, toxic epidermal necrolysis.

**Contraindication**

Mepen is contraindicated in patients who have demonstrated hypersensitivity to this product.

**Precautions**

Patients who have a history of hypersensitivity to carbapenems, penicillins or other beta-lactam antibiotics may also be hypersensitive to Mepen. As with all beta-lactam antibiotics rare hypersensitivity reactions have been reported. Rarely, pseudomembranous colitis has been reported with Mepen as with virtually all antibiotics; therefore, its diagnosis should be considered in patients who develop diarrhoea in association with the use of Mepen. Mepen may reduce serum valproic acid levels. Subtherapeutic levels may be reached in some patients.

**Use in Patients with Liver Disease**

Patients with pre-existing liver disorders should have liver function monitored during treatment with Mepen.

**Drug Interaction**

Probenecid competes with Meropenem for active tubular secretion and thus inhibits the renal excretion of Meropenem with the effect of increasing the elimination half-life and plasma concentration of Meropenem. As the potency and duration of action of Mepen dosed without probenecid are adequate the co-administration of probenecid with Mepen is not recommended. The potential effect of Mepen on the protein binding of other medicines or metabolism has not been studied. However, the protein binding is so low (approximately 2%) that no interactions with other compounds would be expected on the basis of this mechanism. Mepen has been administered concomitantly with many other medications without apparent adverse interaction. Mepen may reduce serum valproic acid levels. Subtherapeutic levels may be reached in some patients. However, no specific drug interaction studies other than with probenecid were conducted.

**Overdosage**

Intentional overdosing of Mepen is unlikely, although overdosing could occur during therapy particularly in patients with renal impairment.

**Pharmaceuticals Precaution**

Special precautions for storage: 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.

**Storage Condition**

Store below at 25$^0$C and dry place, keep away from light. Keep out of reach of children.

**Commercial Pack**

**Mepen 500 mg IV Injection:** Each combi pack contains 1 vial of Meropenem 500 mg as Meropenem with Sodium Carbonate Sterile USP with 1 ampoule of 10 ml water for injection BP, sterile disposable syringe (10 ml) and butterfly needle, 1 alcohol pad, 1 first aid bandage.

**Mepen 1 gm IV Injection:** Each combi pack contains 1 vial of Meropenem 1 gm as Meropenem with Sodium Carbonate Sterile USP with 2 ampoules of 10 ml water for injection BP, sterile disposable syringe (20 ml) and butterfly needle, 1 alcohol pad, 1 first aid bandage.

*Manufactured by*
Popular Pharmaceuticals Ltd. for
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For further query on the use of this medicine, consult to a registered Doctor or Pharmacist.