Meropex

Meropenem USP

Composition
Meropex 1 gm IV injection: Each vial contains sterile Meropenem for injection USP equivalent to 1 gm of Meropenem.

Pharmacology
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. The ease with which it penetrates bacterial cells, its high level of stability to all serine b-lactamases and its marked affinity for the Penicillin Binding Proteins (PBPs) explain the potent bactericidal activity of Meropenem against a broad spectrum of aerobic and anaerobic bacteria. In vitro tests show that Meropenem can act synergistically with various antibiotics. It has been demonstrated both in vitro and in vivo that Meropenem has a post-antibiotic effect against Gram-positive and Gram-negative organisms. The in vitro antibacterial spectrum of Meropenem includes the majority of clinically significant Gram-positive and Gram-negative, aerobic and anaerobic strains of bacteria.

Indication
Meropex is indicated for treatment, in adults and children, of the following infections caused by single or multiple susceptible bacteria and as empiric therapy prior to the identification of the causative organisms:
- Lower Respiratory Tract Infections
- Urinary Tract Infections
- Intra-abdominal Infections
- Gynaecological Infections, including postpartum infections
- Skin and Skin Structure Infections
- Meningitis
- Septicaemia
- Empiric treatment, including initial monotherapy, for presumed bacterial

infections in host-compromised, neutropenic patient because of its broad spectrum of bactericidal activity against Gram-positive and Gram-negative aerobic and anaerobic bacteria, Meropex is effective for the treatment of polymicrobial infections.

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.
Exception:
1. Febrile episodes in neutropenic patients: the dose should be 1 gm every 8 hours.
2. Meningitis: the dose should be 2 gm every 8 hours.

As with other antibiotics, caution may be required in using Meropenem as monotherapy in critically ill patients with known or suspected Pseudomonas aeruginosa associated lower respiratory tract infections. Regular sensitivity testing is recommended when treating Pseudomonas aeruginosa associated infections. Meropex should be given as an intravenous bolus injection over approximately 5 minutes or by intravenous infusion over approximately 15 to 30 minutes (see Method of Administration).
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 recommended 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.
Exception:
1. Febrile episodes in neutropenic patients - the dose should be 20 mg/kg every 8 hours.
2. Meningitis - the dose should be 40 mg/kg every 8 hours. Meropex should be given as an IV bolus over approximately 5 minutes or by intravenous infusion over approximately 15 to 30 minutes. There is no experience in children with renal impairment. Dosage Schedule for Adults with Impaired Renal Function: 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

Meropex is cleared by haemodialysis. If continued treatment with Meropex 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 :
Meropex 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. Meropex 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. Meropex 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.

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

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

Side Effect
Meropex 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, haemolytic anaemia, angioedema, manifestations of anaphylaxis, pseudomembranous colitis, erythema multiforme, Stevens -Johnson syndrome, toxic epidermal necrolysis.

Use in special group :
Pregnancy: Pregnancy category B. The safety of Meropex in human pregnancy has not been established, although animal studies have not shown an adverse effect on the developing foetus. Meropex 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. Meropex 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, Meropex is not recommended for use below this age.

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 Meropex dosed without probenecid are adequate the co-administration of probenecid with Meropex is not recommended. The potential effect of Meropex 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. Meropex has been administered concomitantly with many other medications without apparent adverse interaction. Meropex 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 Meropex is unlikely, although overdosing could occur during therapy particularly in patients with renal impairment. Limited post-marketing experience indicates that if adverse events occur following overdosage, they are consistent with the adverse event profile described in Adverse effects, are generally mild in severity and resolve on withdrawal or dose reduction. Symptomatic treatments should be considered. In normal individuals rapid renal elimination will occur. Haemodialysis will remove Meropex and its metabolite.

Storage
Prior to constitution, store Meropex powder for intravenous injection or infusion packs below 30° C. To reduce microbiological hazard, solutions of Meropex IV should be used as soon as practicable after reconstitution.

Packaging
Meropenem 1 gm IV Injection: Each vial contains sterile Meropenem for injection USP equivalent to 1 gm of Meropenem with 2 ampoules of 10 ml water for injection BP, sterile disposable syringe (20 ml), butterfly needle.

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