Merobac

Meropenem 500 mg & 1 g IV Injection

Presentation
Merobac 500 mg injection: Each vial contains sterile Meropenem USP equivalent to 500 mg anhydrous Meropenem.
Merobac 1 g injection: Each vial contains sterile Meropenem USP equivalent to 1 g anhydrous Meropenem.

Description
Meropenem for injection is a sterile, pyrogen-free, synthetic, broad spectrum, carbapenem antibiotic for intravenous administration. It penetrates bacterial cell walls with its high level of stability to all serine betalactamases and marked affinity for the Penicillin Binding Proteins (PBPs).The bactericidal activity of Meropenem results from the inhibition of cell wall synthesis. Meropenem exerts its action by interfering with the synthesis of vital cell wall components, which leads to cell death. Meropenem is relatively stable to human dehydropeptidase-1 (DHP-1) and therefore, does not require the addition of an inhibitor of DHP-1.

Indications
The in vitro antibacterial spectrum of Meropenem includes the majority of clinically significant Gram-positive and Gram-negative, aerobic and anaerobic strains of bacteria. Meropenem 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 including pneumonias and nosocomial pneumonias, Urinary Tract Infections including complicated infections, Intra-abdominal Infections, Gynaecological Infections including postpartum infections, endometritis and pelvic inflammatory disease, Skin and Skin Structure Infections, Meningitis, Septicaemia, Empiric treatment including initial monotherapy for presumed bacterial infections in host-compromised, neutropenic patients. Because of its broad spectrum of bactericidal activity against Gram-positive and Gram-negative aerobic and anaerobic bacteria Meropenem is effective for the treatment of polymicrobial infections.

Dosage and Administrations
A) Adults: 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: In the treatment of pneumonia, UTI, gynaecological infections such as endometritis, skin and skin structure infections- 500 mg IV every 8 hours. In the treatment of nosocomial pneumonias, peritonitis, presumed infections in neutropenic patients, septicaemia- 1 g IV every 8 hours. In cystic fibrosis- doses up to 2 g every 8 hours. In meningitis- 2 g every 8 hours.

Exceptions: 1. Febrile episodes in neutropenic patients - the dose should be 1 g every 8 hours. 2. Meningitis - the dose should be 2 g 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* lower respiratory tract infections. Regular sensitivity testing is recommended when treating *Pseudomonas aeruginosa* infections. Meropenem should be given as an intravenous bolus injection over approximately 5 minutes or by intravenous infusion over approximately 15 to 30 minutes.

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 g, 2 g 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

Use in Adults with Hepatic Insufficiency: No dosage adjustment is necessary in patients with impaired hepatic metabolism.

B) Elderly:
No dosage adjustment is required for the elderly with normal renal function or creatinine clearance values above 50 mL/min.

C) Children:
For infants and children under 3 months: The efficacy and safety for infants and children under 3 months have not been established, therefore not recommended for such group of patients. 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. 4 years to 18 years with cystic fibrosis: 25 to 40 mg/kg every 8 hours.

Exceptions: 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. Meropenem 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.

Direction of Reconstitution
The content of one vial is to be dissolved in 10 ml Water for injection for Merobac 500 mg IV injection and in 20 ml Water for injection for Merobac 1 g IV injection. As the product dissolves, carbon dioxide is released and a positive pressure develops. For ease of use the following techniques of reconstitution are recommended.

Step 1
Hold the vial in upright position. Remove aproximately 10 ml air from the vial.

Step 2
Add recommended volume of solvent slowly. Hold the syringe plunger tightly. After completion remove the needle. Shake to obtain a clear solution. As the antibiotic dissolves carbon dioxide is released causing frothing which clears quickly.

Step 3
A high pressure inside the vial will be developed. Now, Depress the syringe plunger fully and hold the plunger tightly. Inside the needle to the upright vial up to the neck and withdraw approximately 10 ml of gas.

Step 4
Invert the vial. With a syringe plunger fully depressed, insert the needle keeping it within solution. The pressure aids withdrawal of the solution.

Step 5
Bubble of carbon dioxide in syringe clears quickly on tapping. As these are carbon dioxide, smaller bubbles can be injected without ill effect.

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

Precautions
As with all beta-lactam antibiotics, rare hypersensitivity reactions have been reported. Before initiating therapy with Meropenem, careful inquiry should be made concerning previous hypersensitivity reactions to beta-lactam antibiotics. If an allergic reaction to Meropenem occurs, the drug should be discontinued and appropriate measures should be taken. Use in infections caused by Methicillin resistant staphylococci is not recommended. The co-administration of Meropenem with potentially nephrotoxic drugs should be considered with caution. Rarely, pseudomembranous colitis has been reported with Meropenem as with virtually all antibiotics; therefore, its diagnosis should be considered in patients who develop diarrhoea in association with the use of Meropenem. *Use in children:* Efficacy and tolerability in infants under 3 months old have not been established; therefore, Meropenem is not recommended for use below this age. *Use in patients with liver disease:* Patients with pre-existing liver disorders should have liver function monitored during treatment with Meropenem. *Use in pregnancy:* The safety of Meropenem in human pregnancy has not been established, although animal studies have not shown an adverse effect on the developing foetus. Meropenem should not be used in pregnancy unless the potential benefit justifies the potential risk to the foetus. *Use in 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.

Side Effects
Meropenem is generally well tolerated. Adverse events rarely lead to cessation of treatment. Serious adverse events are rare. The following adverse events may occur: inflammation, thrombophlebitis, pain at the site of injection, skin reactions like rash, pruritus, urticaria etc, abdominal pain, nausea, vomiting, diarrhoea,headache, paraesthesiae.

Drug Interactions
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. So, co-administration of Probenecid with Meropenem is not recommended. The potential effect of Meropenem 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. Meropenem has been administered concomitantly with many other medications without apparent adverse interaction. Meropenem 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 Meropenem is unlikely, although overdosing could occur during therapy particularly in patients with renal impairment. Haemodialysis will remove Meropenem and its metabolite.

Pharmaceutical 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.

Commercial Packs
Merobac 500 mg injection: Each box containing 1 combipack and 10 ml disposable syringe. Each combipack contains one vial of Meropenem 500 mg and one ampoule of 10 ml water for injection.
Merobac 1 g injection: Each box containing 1 combipack and one 20 ml disposable syringe. Each combipack contains one vial of Meropenem 1 g and one ampoule of 20 ml water for injection.

Manufactured by :

POPULAR

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