Specbac® Injection

Meropenem USP

COMPOSITION

Specbac® 500 mg IV injection : Each vial contains Meropenem for Injection USP (as sterile dry mixture of Meropenem and Sodium Carbonate) equivalent to 500 mg of Meropenem and one ampoule contains 10 ml Water for Injections BP (sterile).

Specbac® 1 gm IV injection : Each vial contains Meropenem for Injection USP (as sterile dry mixture of Meropenem and Sodium Carbonate) equivalent to 1 gm of Meropenem and each of two ampoules contains 10 ml Water for Injections BP (sterile).

PHARMACOLOGY

Meropenem is a carbapenem antibiotic for parenteral use that exerts its bactericidal action by interfering with bacterial cell wall synthesis. 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 in vitro antibacterial spectrum of meropenem includes the majority of clinically significant Gram-positive and Gram-negative, aerobic and anaerobic strains of bacteria.

INDICATION

–Pneumonias and Nosocomial Pneumonias
–Urinary Tract Infections
–Intra-abdominal Infections
–Gynaecological Infections, such as endometritis
–Skin and Skin Structure Infections
–Meningitis
–Septicaemia
–Empiric treatment for presumed infections in adult patients with febrile neutropenia
–Other polymicrobial infections

DOSAGE AND ADMINISTRATION

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.
As with other antibiotics, particular caution is recommended in using meropenem as monotherapy in critically ill patients with known or suspected Pseudomonas aeruginosa lower respiratory tract infection. Regular sensitivity testing is recommended when treating Pseudomonas aeruginosa infection.
Patients with Impaired Renal Function-Dosage should be reduced in patients with creatinine clearence less than 51 ml/min, as scheduled below:

Creatinine clearance (ml/min)	Dosage (based on unit doses of 500 mg, 1 gm, 2 gm)	Frequency
25-50	1 unit dose	every 12 hours
10-25	½ unit dose	every 12 hours
<10	½ unit dose	every 24 hours

Patients with Hepatic Insufficiency
No dosage adjustment is necessary in patients with hepatic insufficiency.

Elderly Patients

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

Children

infants under 3 months- Efficacy and tolerability in infants under 3 months old have not been established; therefore, **Specbac**® is not recommended for use below this age.
Children over 3 months
Over 3 months to 12 years - 10 to 20 mg/kg every 8 hours.
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.
In meningitis - 40 mg/kg every 8 hours.
There is no experience in children with altered hepatic or renal function.

CONTRAINDICATION

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

ADVERSE EFFECT

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.

RECONSTITUTION PROCEDURE

The content of one vial is to be dissolved in 10 ml Water for injection for **Specbac**® 500 mg IV injection and in 20 ml Water for injection for **Specbac**® 1 gm 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 approximately 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.

PRECAUTION

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 **Specbac**® with potentially nephrotoxic drugs should be considered with caution.

PREGNANCY AND LACTATION

Pregnancy
Animal studies have not shown any adverse effect on the developing foetus. **Specbac**® 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. **Specbac**® should not be used in breastfeeding women unless the potential benefit justifies the potential risk to the baby.

OVERDOSAGE

Treatment of accidental 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

Store below 30°C. Protect from light and moisture. Keep out of children's reach.
Reconstituted Solution: Please use the solution immediatly after reconstitution.

HOW SUPPLIED

Specbac® 500 mg IV injection : Each pack contains 1 vial of Meropenem 500 mg USP with 1 ampoule of 10 ml Water for Injections BP.

Specbac® 1 gm IV injection : Each pack contains 1 vial of Meropenem 1 gm USP with 2 ampoules of 10 ml Water for Injections BP.

SQUARE