

Specbac® IV Injection

Meropenem USP

PRESENTATION

Specbac® 250 mg IV Injection: Each vial contains sterile dry mixture of Meropenem & Sodium Carbonate equivalent to Meropenem USP 250 mg & each ampoule contains 5 ml sterilised Water for Injections BP.

Specbac® 500 mg IV Injection: Each vial contains sterile dry mixture of Meropenem & Sodium Carbonate equivalent to Meropenem USP 500 mg & each ampoule contains 10 ml sterilised Water for Injections BP.

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

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 wall with its high level of stability to all serine b-lactamases 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

Pneumonia and Nosocomial Pneumonia, 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 gm IV every 8 hours

In cystic fibrosis: doses up to 2 gm every 8 hours & In meningitis: 2 gm every 8 hours.

Particular caution should be taken when using Meropenem with other antibiotics in critically ill patients with known or suspected *Pseudomonas aeruginosa* infections.

Regular sensitivity testing is recommended when treating *Pseudomonas aeruginosa* infection.

Patients 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)	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 patients with normal renal function or creatinine clearance values above 50 ml/min.

Children: Children below 3 months: In Sepsis: 20 mg/kg/dose IV

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

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

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 and paraesthesia.

PREPARATION

Specbac® 250 mg IV injection: Each pack contains one vial of Meropenem USP 250 mg accompanied by one ampoule of 5 ml Water for injection BP with a 10 ml Disposable Syringe, alcohol pad and a set of butterfly needle.

Specbac® 500 mg IV injection: Each pack contains one vial of Meropenem USP 500 mg accompanied by one ampoule of 10 ml Water for injection BP with a 10 ml Disposable Syringe, alcohol pad and a set of butterfly needle.

Specbac® 1 gm IV injection: Each pack contains one vial of Meropenem USP 1 gm accompanied by two ampoules of 10 ml Water for injection BP with a 20 ml Disposable Syringe, alcohol pad and a set of butterfly needle.

Manufactured by



SQUARE

**PHARMACEUTICALS LTD.
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