FULSPEC

IV Injection

Meropenem

COMPOSITION

FULSPEC 250 mg IV Injection: Each vial contains sterile powder of Meropenem USP equivalent to 250 mg Meropenem.
FULSPEC 500 mg IV Injection: Each vial contains sterile powder of Meropenem USP equivalent to 500 mg Meropenem.
FULSPEC 1 g IV Injection: Each vial contains sterile powder of Meropenem USP equivalent to 1 g Meropenem.

PHARMACOLOGY

FULSPEC (Meropenem) is a broad-spectrum carbapenem antibiotic. The bactericidal activity of **FULSPEC** (Meropenem) results from the inhibition of cell wall synthesis. It penetrates the cell wall of most gram-positive and gram-negative bacteria to reach penicillin-binding-protein (PBP) targets. Antibacterial spectrum of **FULSPEC** (Meropenem) includes the majority of clinically significant aerobic and anaerobic strains of gram-positive and gram-negative bacteria. **FULSPEC** (Meropenem) is a white to pale yellow crystalline powder. The solution of **FULSPEC** (Meropenem) varies from colorless to yellow depending on the concentration.

INDICATIONS

- Skin and Skin Structure Infections
- Pneumonia & Hospital Acquired Pneumonia
- Intra-abdominal Infections such as Peritonitis
- Meningitis
- Respiratory Tract Infections in cystic fibrosis patients
- Gynaecological infection, such as endometritis
- Septicemia
- Urinary Tract Infections
- Billiary Tract Infections
- Infections in Immunocompromised Patients (with neutropenia in adults)
- Surgical prophylaxis &
- Other Polymicrobial Infections.

DOSAGE & ADMINISTRATION

Route of administration: Intravenous

Use in Children

Efficacy and tolerability in infants under 3 months old have not been recognized; consequently, **FULSPEC** (Meropenem) is not recommended for below this age.

- **Children over 3 months to 12 years:** 10 to 20 mg/kg body weight every 8 hours.
- **Children over 50 kg body weight:** adult dose.
- **Meningitis:** 40 mg/kg body weight for every 8 hours.
- **Children over 4-18 years with cystic fibrosis:** 25 to 40 mg/kg body weight for every 8 hours.

Adults

It is given by slow intravenous injection over 3 to 5 minutes or by intravenous infusion over 15 to 30 minutes in a usual dose of 500 mg to 1 g every 8 hours.
The recommended daily dosage for adult in:

- **Skin and skin structure infections:** 500 mg IV for every 8 hours.
- **Hospital acquired pneumonia, peritonitis, septicaemia, intra-abdominal infections & infections in neutropenic patients:** 1 g IV for every 8 hours.
- **Meningitis & Infections of chronic lower respiratory tract infections in cystic fibrosis:** 2 g IV for every 8 hours.

Adults with Renal Impairment

Dosage should be reduced in patients with creatinine clearance less than 51 ml/min as below schedule:

Creatinine clearance (ml/min)	Dose (dependent of type of infection)	Dosing interval
≥51	Recommended dose	Every 8 hours
26-50	Recommended dose	Every 12 hours
10-25	½ of recommended dose	Every 12 hours
<10	½ of recommended dose	Every 24 hours

There is no experience in children with renal impairment.

Adults with Hepatic Insufficiency

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

Use in Elderly Patients

No dosage adjustment is required for elderly patients with creatinine clearance values above 50 ml/min.

CONTRAINDICATIONS

Meropenem is contraindicated in patients with known hypersensitivity to this product or other drugs in the same class or in patients who have demonstrated anaphylactic reactions to β-lactams.

WARNING & PRECAUTION

Before initiating therapy with Meropenem careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, other β-lactams, and other allergens. If an allergic reaction to Meropenem occurs, discontinue the drug immediately. Co-administration of Meropenem IV with valproic acid or divalproex sodium reduces the serum concentration of valproic acid potentially increasing the risk of breakthrough seizures. Clostridium difficile-associated diarrhea (ranging from mild diarrhea to fatal colitis) has been reported. Evaluate if diarrhea occurs. In patients with renal dysfunction, thrombocytopenia has been observed

SIDE EFFECTS

Common: Side effects my include Nausea, Vomiting, Diarrhea, Headache, Abdominal Pain, Disturbances In Liver Function Test, Rash, Pruritus, Inflammation may occur.
Rare: Side effects my include burning sensation while Urinating, Cough, Difficulty with Breathing, Hives or Welts, Rapid Weight Gain, Seizures, Stomach Cramps, White Patches in the Mouth, Tongue or Throat

USE IN PREGNANCY & LACTATION

Use in Pregnancy: Pregnancy Category B. Animal studies revealed no evidence of impaired fertility orharm to the fetus due to Meropenem. But there are no adequate and well controlledstudies in pregnant women. So this drug should be used during pregnancy only if clearly needed.
Use in Lactation: Meropenem has been reported to be excreted in human milk. Caution should be exercised when Meropenem is administered to a nursing woman.

USE IN CHILDREN & ADOLESCENTS

The safety and effectiveness of Meropenem IV have been established for pediatric patients 3 months of age and older.

DRUG INTERACTION

With medicine: Probenecid competes with Meropenem for active tubular secretion and thus inhibits the renal excretion of Meropenem. Therefore, the co-administration of probenecid with Meropenem is not recommended.
With food and others: No interaction information available with any food and others

OVERDOSE

Symptomatic treatments should be considered if accidental over dosage occur. In individuals with normal renal function, rapid renal elimination takes place. Meropenem and its metabolite are readily dialyzable and effectively removed by hemodialysis.

RECONSTITUTION PROCEDURE

The content of one vial is to be dissolved in 5 ml water for injection for FULSPEC (Meropenem) 250 mg IV injection, 10 ml water for injection for FULSPEC (Meropenem) 500 mg IV injection and in 20 ml water for injection for FULSPEC (Meropenem) 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 approximately 10 ml air from thevial.
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.
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.

STORAGE

Before mixing, store the dry powder of FULSPEC (Meropenem) at temperature between 20^0-25^0C away from light and moisture. After mixing, constituted solutions may be stored for up to 2 hours at controlled room temperature 15^0-25^0C or for up to 12 hours at 4^0C if required. However, freshly prepared solution of FULSPEC (Meropenem) should be used whenever possible.

PACKING

FULSPEC 250 mg IV Injection: Each pack contains a blister strip of one vial of Meropenem 250 mg Injection with one ampoule of 5 ml Water for Injection and a complementary pouch. Complementary pouch contains a 5 ml disposable syringe, an alcohol pad, a baby needle and first aid bandage.

FULSPEC 500 mg IV Injection: Each pack contains a blister strip of one vial of Meropenem 500 mg Injection with one ampoule of 10 ml Water for Injection and a complementary pouch. Complementary pouch contains a 10 ml disposable syringe, an alcohol pad, a set of butterfly needle and first aid bandage.

FULSPEC 1 g IV Injection: Each pack contains a blister strip of one vial of Meropenem 1 g Injection with two ampoules of 10 ml Water for Injection and complementary pouch. Complementary pouch contains a 20 ml disposable syringe, an alcohol pad and a set of butterfly needle.

Keep all medicines out of reach of children.

**** Further information is available on request.***

Manufactured by:
The ACME Laboratories Ltd.
Dhamrai, Dhaka, Bangladesh
For Health, Vigour and Happiness