MEROXIN

Meropenem

COMPOSITION

MEROXIN 500 mg IV Injection: Each vial contains sterile powder of Meropenem for Injection USP equivalent to Meropenem 500 mg.
MEROXIN 1 gm IV Injection: Each vial contains sterile powder of Meropenem for Injection USP equivalent to Meropenem 1 gm.

PHARMACOLOGY

Meropenem is a carbapenem antibiotic for parenteral use . It exerts its bactericidal action by interfering with bacterial cell wall synthesis. It penetrates bacterial cell walls, its high level of stability to all serine beta-lactamases and its marked affinity for the Penicillin Binding Proteins (PBPs.). It shows potent bactericidal activity against a broad spectrum of Gram-positive and Gram-negative, aerobic and anaerobic bacteria.

INDICATIONS

Meropenem IV is indicated for treatment in adults and children for the following infections caused by single or multiple bacteria sensitive to Meropenem.

- Pneumonia and Nosocomial Pneumonia
- Urinary Tract Infections
- Intra-abdominal Infections
- Gynaecological Infections, such as endometritis and pelvic inflammatory disease
- Skin and Skin Structure Infections
- Meningitis
- Septicaemia
- Pulmonary infections in cystic fibrosis
- Empiric treatment for presumed infections in patients with febrile neutropenia

DOSAGE AND ADMINISTRATION

The dosage and duration of therapy shall be established depending on type, severity of infection and the condition of the patient.
The recommended daily dosage is as follows:-
Adults:
The usual dose is 500 mg to 1 gm by intravenous administration every 8 hours.
Pneumonia, urinary tract infections, gynaecological infections such as endometritis, pelvic inflammatory disease, skin and skin structure infections: 500 mg IV every 8 hours.
Nosocomial pneumonias, peritonitis, presumed infections in neutropenic patients and septicaemia: 1gm IV every 8 hours.
Intra-abdominal infections: 500 mg to 1 gm every 8 hours.
Cystic fibrosis: Upto 2 gm every 8 hours.
Meningitis: 2 gm IV every 8 hours.
Renal impairment:
Dosage should be reduced in patients with creatinine clearance less than 51 ml/min. Recommended **MEROXIN IV** dosage schedule for adult patients with renal impairment

Creatinine Clearance (ml/min)	Dose (dependent on type of infection)	Dosing Interval
26-50	Recommended dose	Every 12 hours
10-25	One-half of recommended dose	Every 12 hours
Less than 10	One-half of recommended dose	Every 24 hours

Hepatic impairment: No dosage adjustments are necessary with impairment of liver function. Hemodialysis patients should receive Meropenem after dialysis has been completed.
Elderly: No dosage adjustments are necessary in elderly patients unless creatinine clearance is <51 ml/min.
Children:
3 months to 12 years: 10 to 40 mg/kg intravenously every 8 hours depending on type and severity of infection, susceptibility of the pathogens and the condition of the patient.
Intra-abdominal infections: 20 mg/kg every 8 hours.
Cystic fibrosis (4-18 years): 25-40 mg/kg every 8 hours.
Meningitis: 40 mg/kg IV every 8 hours.
Febrile neutropenia: 20 mg/kg every 8 hours.
Children over 50 kg weight: use adult dosage.
There is no experience in children with hepatic or renal impairment.
MEROXIN IV should be administered by intravenous Infusion over approximately 15-30 minutes or as intravenous bolus (5 to 20 ml) over approximately 3-5 minutes.
Preparation of solution:
Intravenous bolus Administration:
Reconstitute **MEROXIN IV** injection (500 mg or 1 gm) with sterile water for injection. Shake to dissolve and to obtain solution which is clear and colorless or pale yellow. Amount of water for injection would be as follows:

Vial Size	Water for injection (ml)	Approximate Average Concentration (mg/ml)
500 mg	10	50
1 gm	20	50

Intravenous infusion administration:
Meropenem 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.
Compatible infusion fluid
Meropenem 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, normosol-M in 5% Glucose intravenous infusion.

(The use of freshly reconstituted solution is recommended. However, it maintains potency for up to 3 hours at up to 25^{O}C or 13 hours at up to 5^{O}C)

USE IN SPECIAL GROUP

Use in Pregnancy: Pregnancy Category B. There are no adequate and well-controlled studies in pregnant women. So this drug should be used during pregnancy only if clearly needed.
Use in Lactation: Because many drugs are excreted in human milk, caution should be exercised when Meropenem is administered to a nursing woman.
Use in Children: Efficacy and tolerability in infants under 3 months have not been established.

CONTRAINDICATIONS

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

WARNING AND PRECAUTION

If an allergic reaction to Meropenem occurs, the drug should be discontinued and appropriate measures taken. Use of Meropenem in patients with hepatic disease should be made with careful monitoring of transaminase and bilirubin levels.

SIDE EFFECTS

Meropenem is generally well tolerated. Side effects like inflammation, thrombophlebitis, pain at the site of injection, skin reactions like rash, pruritus, urticaria, abdominal pain, nausea, vomiting, diarrhea, headache may occur.

USE IN PREGNANCY AND LACTATION

There is insufficient data regarding its use in pregnancy.
However, meropenem is excreted in breast milk and should be used with caution.

USE IN CHILDREN AND ADOLESCENTS

Safety and efficacy have not been established under the age of 3 months.

DRUG INTERACTIONS

Probenecid competes with Meropenem for active tubular secretion and thus inhibits the renal excretion, with the effect of increasing the elimination half-life and plasma concentration of meropenem. Meropenem may reduce serum valproic acid levels. Sub therapeutic levels may be reached in some patients.

OVERDOSAGE

Accidental overdose could occur during therapy, particularly in patients with renal impairment. Treatment of overdose 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^{O}C temperature in a cool and dry place. Protect from light and moisture. Keep out of the reach of children.

HOW SUPPLIED

MEROXIN 500 mg IV Injection: Each combipack contains one vial containing sterile powder of Meropenem for Injection USP equivalent to Meropenem 500 mg and one ampoule of 10 ml Water for Injection USP. It also contains a complementary pouch comprised of disposable syringe (10 ml), butterfly needle, alcohol pad and first aid bandage.
MEROXIN 1 gm IV Injection: Each combipack contains one vial containing sterile powder of Meropenem for Injection USP equivalent to Meropenem 1 gm and two ampoules of 10 ml Water for Injection USP. It also contains a complementary pouch comprised of disposable syringe (20 ml), butterfly needle, alcohol pad and first aid bandage.

02184/00

NIPRO JMI Pharma

Manufactured by:
NIPRO JMI Pharma Ltd.
Chauddagram, Cumilla, Bangladesh.