

# Penomer®

Meropenem  
IV Injection

## Description

Penomer® (Meropenem) is a broad-spectrum carbapenem antibiotic. It is active against Gram-positive and Gram negative bacteria. The bactericidal activity of Meropenem results from the inhibition of cell wall synthesis. Meropenem readily penetrates the cell wall of most Gram-positive and Gram-negative bacteria to reach penicillin binding-protein (PBP) targets. Its strongest affinities are toward PBPs 2, 3 and 4 of *Escherichia coli* and *Pseudomonas aeruginosa*; and PBPs 1, 2 and 4 of *Staphylococcus aureus*. Bactericidal concentrations (defined as a 3 log<sub>10</sub> reduction in cell counts within 12 to 24 hours) are typically 1-2 times the bacteriostatic concentrations of Meropenem.

Meropenem has significant stability to hydrolysis by  $\beta$ -lactamases of most categories, both penicillinases and cephalosporinases produced by Gram-positive and Gram-negative bacteria. Meropenem should not be used to treat methicillin-resistant staphylococci (MRSA). In vitro tests show meropenem to act synergistically with aminoglycoside antibiotics against some isolates of *Pseudomonas aeruginosa*.

## Indications

Complicated Skin and Skin Structure Infections

Intra-abdominal Infections

Bacterial Meningitis (Pediatric patients > 3 months only)

Community-Acquired Pneumonia and Nosocomial Pneumonia

Febrile Neutropenia

Urinary Tract Infections

Gynaecological Infections, such as endometritis and pelvic inflammatory disease.

## Contraindications

Meropenem is contraindicated in patient with known hypersensitivity to any component of this product or to other drugs in the same class or in patients who have demonstrated anaphylactic reactions to  $\beta$ -lactams.

## Dosage and Administration

Adults: The adult dose is 500 mg to 1 g by intravenous infusion over 15-30 minutes or as intravenous bolus (5 to 20 ml) over 3-5 minutes every 8 hours.

Pneumonia, urinary tract infections, gynaecological infections such as endometritis, skin and skin structure infections: 500 mg IV every 8 hours.

Nosocomial pneumonias, peritonitis, presumed infections in neutropenic patients and septicemia: 1g IV every 8 hours. Intra-abdominal infections: 500 mg to 1 g every 8 hours. Meningitis: 2 g IV every 8 hours.

Children: Complicated skin and skin structure infections: 10 mg/kg (maximum of 500 mg) every 8 hours;

Intra-abdominal infections: 20 mg/kg (maximum of 1 g) Every 8 hours;

Meningitis: 40 mg/kg (maximum of 2 g) Every 8 hours.

## Reconstitution

For 500 mg IV injection dissolve contents of vial in 10 ml water for injection vigorously. For 1 g IV injection dissolve contents of vial in 20 ml water for injection vigorously. Vials constituted

with sterile Water for Injection for bolus administration may be stored for up to 2 hours at controlled room temperature 15-25°C (59-77°F) or for up to 12 hours at 4°C (39°F). Intravenous bolus injection should be administered over approximately 3-5 minutes.

Infusion vials constituted with Sodium Chloride Injection 0.9% (concentrations ranging from 2.5 to 50 mg/ml) are stable for up to 2 hours at controlled room temperature 15-25°C (59-77°F) or for up to 18 hours at 4°C (39°F). Intravenous infusion should be administered over approximately 15-30 minutes.

#### Adverse Reactions

The most common adverse reactions (>2%) are nausea, headache, diarrhea, vomiting, and dizziness.

#### Precautions

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.

Meropenem has been associated with headache, tingling or pricking skin and convulsions. Any of this could affect the ability to drive or operate machines. If you have a condition which requires you to monitor your sodium intake please inform your doctor or nurse because Meropenem contains sodium.

#### Side Effects

Seizures and other adverse CNS experiences have been reported during treatment with Meropenem injection. These experiences have occurred most commonly in patients with CNS disorders (e.g., brain lesions or history of seizures) or with bacterial meningitis and/or compromised renal function.

#### Use in Special Population

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

Renal Impairment Patients: Dosage should be reduced in patients with creatinine clearance less than 51 ml/min. (see dosing table below).

#### Recommended Dosage Schedule for Adults with Impaired Renal Function

Creatinine Clearance (ml/min)	Dose	Dosing Interval
26- 50	Recommended dose	Every 12 hours
10 -25	One-half recommended dose	Every 12 hours
<10	One-half recommended dose	Every 24 hours

Elderly Patients: No dosage adjustment is required for elderly patients with creatinine clearance values above 50 ml/min. Pediatric Patients: For pediatric patients from 3 months of age and older.

#### Drug Interaction

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.

### Use in Pregnancy and Lactation

Pregnancy: Category B. this drug should be used during pregnancy only if clearly needed.

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.

### Overdose

Accidental overdosage could occur during therapy, particularly in patients with renal impairment. Treatment of overdosage should be symptomatic. In normal individuals, rapid renal elimination will occur; in subjects with renal impairment, haemodialysis will remove meropenem and its metabolite.

### Pharmaceutical Precautions

Keep out of the reach of children. Keep in a cool & dry place. Protect from light.

### Commercial Pack

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

Penomer® 1 g IV injection: Each combipack contains one vial of Meropenem for Injection (Sterile dry mixture of Meropenem and Sodium Carbonate) USP equivalent to Meropenem 1 g and one ampoule of 20 ml Water for Injection BP.

**BEXIMCO PHARMACEUTICALS LTD.**

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