

# **Meroject®**

Meropenem for Injection USP

## **DESCRIPTION**

**Meroject®** is a preparation of meropenem. **Meroject®** is a broad-spectrum Carbapenem antibiotic. It is active against Gram-positive and Gram-negative bacteria. The bactericidal activity of **Meroject®** results from the inhibition of cell wall synthesis. **Meroject®** readily penetrates the cell wall of most Gram-positive and Gram-negative bacteria to reach penicillin binding-protein (PBP) targets. **Meroject®** has significant stability to hydrolysis by beta-lactamases of most categories, both penicillinases and Cephalosporinases produced by Gram-positive and Gram-negative bacteria.

## **INDICATIONS**

- Skin and skin structure infections
- Complicated intra-abdominal infections
- Bacterial meningitis
- Pneumonias
- Urinary Tract Infections
- Hospital acquired septicaemia
- Obstetric and gynecologic infections
- Exacerbations of chronic lower respiratory tract infection in cystic fibrosis
- Endocarditis (in combination with another antibacterial)

## **DOSAGE AND ADMINISTRATION**

- 500 mg every 8 hours by intravenous infusion over 15 to 30 minutes for skin and skin structure infections for adult patients. When treating infections caused by *Pseudomonas aeruginosa*, a dose of 1 gram every 8 hours is recommended.
- 1 gram every 8 hours by intravenous infusion over 15 minutes to 30 minutes for intra-abdominal infections for adult patients.
- 1 gram every 8 hours by intravenous bolus injection (5 mL to 20 mL) over 3 minutes to 5 minutes for adult patients.

Recommended Meropenem IV dosage schedule for adult patients with renal impairment:

Creatinine Clearance (mL/min)	Dose (dependent on type of infection) (based on unit doses of 500 mg, 1 g, 2 g)	Frequency
Greater than 50	1 unit dose	Every 8 hours
26-50	1 unit dose	Every 12 hours
10-25	1/2 unit dose	Every 12 hours
Less than 10	1/2 unit dose	Every 24 hours

Recommended Meropenem IV dosage schedule for pediatric patients 3 months of age and older with normal renal function:

- Children 3 months of age and older – 10 to 40 mg/kg depending on type of infection
- Children over 50 kg weight – adult dose to be used

There is no experience in pediatric patients with renal impairment.

### **Note:**

- > Intravenous infusion is to be given over approximately 15 minutes to 30 minutes.
- > Intravenous bolus injection (5 mL to 20 mL) is to be given over approximately 3 minutes-5 minutes.
- Recommended Meropenem IV dosage schedule for pediatric patients less than 3 months of age with complicated intra-abdominal infections and normal renal function:

<b>Age Group</b>	<b>Dose (mg/kg)</b>	<b>Dose Interval</b>
Infants less than 32 weeks GA and PNA less than 2 weeks	20	Every 12 hours
Infants less than 32 weeks GA and PNA 2 weeks and older	20	Every 8 hours
Infants 32 weeks and older GA and PNA less than 2 weeks	20	Every 8 hours
Infants 32 weeks and older GA and PNA 2 weeks and older	30	Every 8 hours

#### **Note:**

- > Intravenous infusion is to be given over 30 minutes.
- > There is no experience in pediatric patients with renal impairment. GA: gestational age and PNA: postnatal age.

#### **CONTRAINDICATIONS**

Known hypersensitivity to product components or anaphylactic reactions to  $\beta$ -lactams

#### **WARNING AND PRECAUTIONS**

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients receiving  $\beta$ -lactams. Seizures and other adverse CNS experiences have been reported during treatment. 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. If an allergic reaction to Meropenem occurs, the drug should be discontinued and appropriate measures should be taken.

#### **SIDE-EFFECTS**

- Headache
- Nausea and Vomiting
- Constipation
- Diarrhea
- Anemia
- Rash

#### **USE IN PREGNANCY AND LACTATION**

Pregnancy category B. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. Meropenem has been reported to be excreted in human milk. Caution should be exercised when Meropenem IV injection is administered to a nursing woman.

#### **PHARMACEUTICAL PRECAUTION**

Keep away from wet place & light, store below 30 °C temperature. Keep out of reach of children.

#### **PACKAGING**

**Meroject® 500 IV Injection:** Box containing one vial of sterile Meropenem (anhydrous) USP 500 mg and Sodium 45 mg as Sodium Carbonate and one ampoule of 10 mL sterile Water for Injection USP as solvent.

**Meroject® 1 g IV Injection:** Box containing one vial of sterile Meropenem (anhydrous) USP 1 g and Sodium 90 mg as Sodium Carbonate and two ampoules of 10 mL sterile Water for Injection USP each as solvent.

#### **SK+F**

Manufactured by

**ESKAYEF PHARMACEUTICALS LTD.**

RUPGANJ, NARAYANGANJ, BANGLADESH

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