SK+F
ESKAYEF PHARMACEUTICALS LTD.
Murapara, Rupganj, Narayanganj 1464, Bangladesh.

Packaging Material Code: R/PM0284
Version No.: V03

W - 80 mm

L - 155 mm

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:
> Reconstituted solution is to be used immediately after preparation. It can be used within 2 hours if stored at or below 25 °C temperature and within 4 hours if stored at refrigerator (2 °C to 8 °C).
> 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:

W - 80 mm

Age Group	Dose (mg/kg)	Dose Interval
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 β-lactams

WARNING AND PRECAUTIONS
Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients receiving β-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. • To be dispensed and sold only on the prescription of a registered physician. • Should not be used more than the mentioned amount in the prescription. • The solution should not be used if it is found to be turbid or sedimented after reconstitution.

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
Do not store above 25 °C temperature. Keep away from light & wet place. Keep out of reach of children.

PACKAGING
Meroject® 250 IV Injection: Box containing one vial of sterile Meropenem (anhydrous) USP 250 mg and Sodium 22.5 mg as Sodium Carbonate and one ampoule of 5 mL sterile Water for Injection USP as solvent.

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
® REGD. TRADEMARK
R/PM0284 V03

PM SPECIFICATION

Creative ID: CSD_04

Job Name: Meroject Injection Leaflet		**Size:**W - 80 mm, L - 155 mm	**Paper:** 60 gsm Offset Paper
No. of Color: 2 (Extra)	**Lamination:** N/A	**Loading Process:** N/A	**Others:** N/A
Process Color Print: YES	**Pantone Color Code**	Black 6 U	3546 U

Job Name : Meroject Injection Leaflet

	Creative Service Department	Marketing Department	PD/QC/Contract Customer	Approved By
Comments				
Signature & Date				