For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Abridged Prescribing Information

Meropenem Injection IP

M-Nem™

COMPOSITION

M-Nem™ 500 mg : Meropenem Trihydrate I.P. equivalent to Anhydrous Meropenem 500mg , Sodium Carbonate I.P. equivalent to Sodium 45.1mg (as buffer)

M-Nem™ 1000 mg :Meropenem Trihydrate IP equivalent to Anhydrous Meropenem 1000 mg, Sodium Carbonate I.P. equivalent to Sodium 90.2 mg (as buffer)

THERAPEUTIC INDICATIONS: For the treatment of the following infections in adults and children above 3 months of age : Pneumonia, including community acquired pneumonia and nosocomial pneumonia, bronchopulmonary infections in cystic fibrosis, complicated urinary tract infections, complicated intraabdominal infections, intra and postpartum infections, complicated skin and soft tissue infections, acute bacterial meningitis, management of febrile neutropenic patients.

DOSAGE AND METHOD OF ADMINISTRATION: The dose of meropenem administered and the duration of treatment should take into account the type of infection to be treated, including its severity, and the clinical response. A dose of up to 2 g three times daily in adults and adolescents and a dose of up to 40 mg/kg three times daily in children may be particularly appropriate when treating some types of infections, such as infections due to less susceptible bacterial species or very severe infections. Additional considerations for dosing are needed when treating patients with renal insufficiency. No dose adjustment is necessary in patients with hepatic impairment. In children over 50 kg body weight, the adult dose should be administered. Meropenem is usually given by intravenous infusion over approximately 15 to 30 minutes. Alternatively, meropenem doses of up to 20 mg/kg may be given as an intravenous bolus over approximately 5 minutes. There are limited safety data available to support the administration of a 40 mg/kg dose in children as an intravenous bolus injection.

SAFETY RELATED INFORMATION

CONTRAINDICATIONS: M-Nem ™ is contraindicated in patients with known hypersensitivity to any component of this product or to any other carbapenem antibacterial agent, severe hypersensitivity (e.g. anaphylactic reaction, severe skin reaction) to any other type of beta-lactam antibacterial agent (e.g. penicillins or cephalosporins)

WARNINGS AND PRECAUTIONS: Resistance to penems of *Enterobacteriaceae, Pseudomonas aeruginosa, Acinetobacter* spp. Prescribers are advised to take into account the local prevalence of resistance in these bacteria to penems. As with all beta-lactam antibiotics, serious and occasionally fatal hypersensitivity reactions have been reported. If severe allergic reaction occurs discontinue the product and take appropriate measures. Antibiotic-associated colitis and pseudomembranous colitis have been reported with meropenem, and may range in severity from mild to life threatening. Medicinal products that inhibit peristalsis should not be given. Seizures have infrequently been reported during treatment with carbapenems, including meropenem. Hepatic function should be closely monitored during treatment with meropenem due to the risk of hepatic toxicity, there is no dose adjustment necessary. A positive direct or indirect Coombs test may develop during treatment with meropenem. The concomitant use of meropenem and valproic acid/sodium valproate/valpromide is not recommended. Sodium content should be taken into consideration by patients on a controlled sodium diet. Severe cutaneous adverse reactions (SCAR) such as Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), erythema multiforme (EM) and acute generalized exanthematous pustulosis (AGEP) have been reported in patients receiving meropenem. If signs and symptoms suggestive of these reactions appear, Meropenem should be withdrawn immediately and an alternative treatment should be considered. Rhabdomyolysis has been reported with the use of meropenem. If signs or symptoms of rhabdomyolysis are observed, meropenem should be discontinued and appropriate therapy initiated.

PREGNANCY: It is preferable to avoid the use of meropenem during pregnancy.

LACTATION: Meropenem should not be used in breast feeding women unless the potential benefit for the mother justifies the potential risk to the baby.

ADVERSE REACTIONS: In a review most frequently reported adverse reactions were : diarrhoea (2.3 %), rash (1.4 %), nausea/vomiting (1.4 %) and injection site inflammation (1.1 %). The most commonly reported meropenem-related laboratory adverse events were thrombocytosis (1.6 %) and increased hepatic enzymes (1.5-4.3 %). Common adverse reactions are (≥ 1/100 to <1/10): thrombocythaemia, headache, diarrhoea, vomiting, nausea, abdominal pain, transaminases increased, blood alkaline phosphatase increased, blood lactate dehydrogenase increased, rash, pruritus, inflammation, pain

For full prescribing information, please contact Sanofi India Limited, Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai - 72.

Source:

- Summary of Product Characteristics for Meronem IV 500 mg and Meronem IV 1000 mg dated July 2025 (accessed on 31st July 2025). (**Meropenem 500 mg Powder for Solution for Injection or Infusion - Summary of Product Characteristics (SmPC) - print friendly - (emc)**)
- Scientific conclusions and grounds for the variation to the terms of the Marketing Authorisation(s)-PRAC recommendation (DILI related)Prescribing Information for Merocrit I.V Injection dated October 2013 (for indications)

Updated: August 2025