Merokem I.V ®

Merokem I.V.
(meropenem) for Injection

FOR INTRAVENOUS USE ONLY

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Merokem I.V. (meropenem for injection) and other antibacterial drugs, MERREM I.V. should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

Each 500 mg MERREM I.V. vial will deliver 500 mg meropenem and 45.1 mg of sodium as sodium carbonate (1.96 mEq).

INDICATIONS

To reduce the development of drug-resistant bacteria and maintain the effectiveness of MERREM I.V. and other antibacterial drugs, MERREM I.V. should only be used to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

MERREM I.V. is indicated as single agent therapy for the treatment of the following infections when caused by susceptible isolates of the designated microorganisms:
Skin and Skin Structure Infections

Complicated skin and skin structure infections due to Staphylococcus aureus (ß-lactamase and non-ß- lactamase producing, methicillin susceptible isolates only), Streptococcus pyogenes, Streptococcus agalactiae, viridans group streptococci, Enterococcus faecalis (excluding vancomycin-resistant isolates), Pseudomonas aeruginosa, Escherichia coli, Proteus mirabilis, Bacteroides fragilis, and Peptostreptococcus species.
Intra-abdominal Infections

Merokem I.V ®

Complicated appendicitis and peritonitis caused by viridans group streptococci, Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Bacteroides fragilis, B. thetaiotaomicron, and Peptostreptococcus species.
MERREM I.V. has been found to be effective in eliminating concurrent bacteremia in association with bacterial meningitis.MERREM I.V. is useful as presumptive therapy in the indicated condition (i.e., intra-abdominal infections) prior to the identification of the causative organisms because of its broad spectrum of bacterial activity.

DOSAGE AND ADMINISTRATION

Adults

The recommended dose of MERREM I.V. is 500 mg given every 8 hours for skin and skin structure infections and 1 g given every 8 hours for intra-abdominal infections. MERREM I.V. should be administered by intravenous infusion over approximately 15 to 30 minutes. Doses of 1 g may also be administered as an intravenous bolus injection (5 to 20 mL) over approximately 3-5 minutes.

Use in Elderly Patients

No dosage adjustment is required for elderly patients with creatinine clearance values above 50 mL/min.

Use in Pediatric Patients

For pediatric patients from 3 months of age and older, the MERREM I.V. dose is 10, 20 or 40 mg/kg every 8 hours (maximum dose is 2 g every 8 hours), depending on the type of infection (complicated skin and skin structure, intra-abdominal or meningitis). (See dosing table below.) Pediatric patients weighing over 50 kg should be administered MERREM I.V. at a dose of 500 mg every 8 hours for complicated skin and skin structure infections, 1 g every 8 hours for intra-abdominal infections and 2 g every 8 hours for meningitis. MERREM I.V. should be given as intravenous infusion over approximately 15 to 30 minutes or as an intravenous bolus injection (5 to 20 mL) over approximately 3-5 minutes.

MEROKEM I.V 1000mg
Meropenem Injection

TAJ GROUP
PHARMA BUSINESS
WORLDWIDE

Merokem I.V ®

WARNINGS

SERIOUS AND OCCASIONALLY FATAL HYPERSENSITIVITY (ANAPHYLACTIC) REACTIONS HAVE BEEN REPORTED IN PATIENTS RECEIVING THERAPY WITH ß-LACTAMS. THESE REACTIONS ARE MORE LIKELY TO OCCUR IN INDIVIDUALS WITH A HISTORY OF SENSITIVITY TO MULTIPLE ALLERGENS.

THERE HAVE BEEN REPORTS OF INDIVIDUALS WITH A HISTORY OF PENICILLIN HYPERSENSITIVITY WHO HAVE EXPERIENCED SEVERE HYPERSENSITIVITY REACTIONS WHEN TREATED WITH ANOTHER ß-LACTAM. BEFORE INITIATING THERAPY WITH MERREM I.V., CAREFUL INQUIRY SHOULD BE MADE CONCERNING PREVIOUS HYPERSENSITIVITY REACTIONS TO PENICILLINS, CEPHALOSPORINS, OTHER ß-LACTAMS, AND OTHER ALLERGENS. IF AN ALLERGIC REACTION TO MERREM I.V. OCCURS, DISCONTINUE THE DRUG IMMEDIATELY. SERIOUS ANAPHYLACTIC REACTIONS REQUIRE IMMEDIATE EMERGENCY TREATMENT WITH EPINEPHRINE, OXYGEN, INTRAVENOUS STEROIDS, AND AIRWAY MANAGEMENT, INCLUDING INTUBATION. OTHER THERAPY MAY ALSO BE ADMINISTERED AS INDICATED.

CONTRAINDICATIONS

MERREM I.V. is contraindicated in patients 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 ß-lactams.

Presentation

Meterra Injection	Each 2 ml Injection