Meropenem for Injection BP 1g

Para uso IM/IV

Composition: Each vial contains:
Meropenem trihydrate BP
equivalent to anhydrous meropenem 1 g
Sodium carbonate BP
equivalent to sodium 90.2 mg
Sterile water for injections BP 10 ml

Therapeutic indications: Meropenem is indicated for the treatment of the following infections in adults and children aged 3 months and older:
Severe pneumonia, including hospital-acquired and ventilator-associated pneumonia.
Bronchopulmonary infections in cystic fibrosis
Complicated urinary tract infections
Complicated intra-abdominal infections
Intra- and post-partum infections
Complicated skin and soft-tissue infections
Acute bacterial meningitis
Meropenem may be used in the management of neutropenic patients with fever suspected to be due to a bacterial infection.

Posology and method of administration
Posology:
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 certain types of infections, such as infections caused by less susceptible bacterial species or very severe infections.
Paediatric population
Children under 3 months of age
The safety and efficacy of meropenem in children under 3 months of age have not been established and the optimal dosage regimen has not been identified. However, limited pharmacokinetic data suggest that 20 mg/kg every 8 hours may be an appropriate regimen.

Method of administration
Meropenem is usually administered by intravenous infusion over approximately 15 to 30 minutes.
Alternatively, meropenem doses of up to 20 mg/kg may be administered as an intravenous bolus over approximately 5 minutes. Limited safety data are available to support the administration of a 40 mg/kg dose in children as an intravenous bolus injection.

Contraindications
Hypersensitivity to the active substance or to any of the excipients.
Hypersensitivity 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).

Special warnings and precautions for use
The choice of meropenem to treat an individual patient should take into account the suitability of using a carbapenem antibacterial agent based on factors such as: the severity of the infection, the prevalence of resistance to other suitable antibacterial agents, and the risk of selecting for carbapenem-resistant bacteria.
If a severe allergic reaction occurs, the medicinal product must be discontinued and appropriate measures taken.
Contains sodium.
Meropenem 1 g: This medicinal product contains approximately 4 mEq of sodium per 1 g dose, which should be taken into consideration by patients on a controlled sodium diet.

Interaction with other medicinal products and other forms of interaction
No specific drug interaction studies have been conducted, except with probenecid.
Oral anticoagulants
Co-administration of antibiotics with warfarin may enhance its anticoagulant effects.
Pediatric population
Interaction studies have only been performed in adults.

Pregnancy and breastfeeding
Pregnancy
As a precautionary measure, it is preferable to avoid the use of meropenem during pregnancy.
Breastfeeding
Small amounts of meropenem have been reported to be excreted in human milk. Meropenem should not be used in breastfeeding women unless the potential benefit to the mother justifies the potential risk to the infant.

Undesirable effects
Blood and lymphatic system disorders: thrombocythemia. Nervous system disorders: headache.
Skin and subcutaneous tissue disorders: rash, pruritus.
General disorders and administration site conditions: inflammation, pain.

Overdose
Relative overdose may occur in patients with renal impairment if the dose is not adjusted. Limited post-marketing experience indicates that if adverse reactions occur following overdose, they are consistent with the known adverse reaction profile, are generally mild in severity, and resolve upon discontinuation or dose reduction. Symptomatic treatment should be considered. In individuals with normal renal function, rapid renal elimination occurs. Hemodialysis will remove meropenem and its metabolite.

Storage:
Store below 30°C. Protect from sunlight.

Keep medicines out of the reach of children.

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