

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

## **MERONEM for Intravenous Administration**

### **Composition**

Vials containing 500 mg or 1g meropenem

### **Therapeutic Uses**

Meropenem, a carbapenem antibiotic, is indicated for the treatment of the following severe to serious infections: pneumonias including nosocomial pneumonias, urinary tract infections, intra-abdominal infections, gynaecological infections such as endometritis and pelvic inflammatory disease, skin and skin structure infections, meningitis, septicaemia and empiric treatment, for presumed infections in adult patients with febrile neutropenia.

### **Antibacterial spectrum**

The in-vitro antibacterial spectrum of meropenem includes the majority of clinically significant Gram-positive and Gram-negative, aerobic and anaerobic strains. For specific bacteria consult full prescribing information.

### **Dosage and administration**

The dosage and duration of therapy should be established depending on type and severity of infection and the condition of the patient. Adjust dosage in renal impairment (consult full prescribing information) Adults: Pneumonia, urinary tract infections, gynaecological infections such as endometritis, skin and skin structure infections: 500 mg i.v. every 8 hours. Nosocomial pneumonias, peritonitis, presumed infections in neutropenic patients and septicaemia: 1g i.v. every 8 hours. Meningitis: 2g i.v. every 8 hours. No dosage adjustment is required for the elderly with normal renal function or creatinine clearance values above 50 ml/min. Renal impairment: Reduce dosage if creatinine clearance less than 51 ml/min (consult full prescribing information). Children: Children 0-3 months: no data therefore not recommended. Children 3 months -12 years: 10-20 mg/kg i.v. every 8 hours depending on type and severity of infection, susceptibility of the pathogen(s) and the condition of the patient. Children over 50kg weight: use adult dosage. Meningitis: 40mg/kg i.v. every 8 hours. There is no experience in children with hepatic or renal impairment.

### **Administration**

Following reconstitution; Meronem should be given as an intravenous bolus injection over approx. 5 minutes or by intravenous infusion over approx. 15 to 30 minutes. Refer to full prescribing information for infusion fluids. Bolus: Meronem should be reconstituted with sterile water for injections (5ml per 250mg meropenem). This provides an approximate concentration of 50mg/ml. Infusion: Meronem may be reconstituted with compatible infusion fluids (50-200ml) (consult full prescribing information for infusion fluids).

### **Contraindications and precautions**

Contra-indicated in patients with hypersensitivity to the product. Caution in patients with history of hypersensitivity to carbapenems or other beta-lactam antibiotics. Monitor transaminase and bilirubin levels when used in hepatic disease.

Not recommended for methicillin-resistant staphylococci infections. Monitor for overgrowth of non-susceptible organisms. In patients who develop diarrhoea, consider diagnosis of pseudomembranous colitis. Caution in individuals with a history of gastro-intestinal complaints, particularly colitis. Caution if to be co-administered with potentially nephrotoxic drugs. Co-administration with probenecid not recommended. Meronem may reduce serum valproic acid levels, sub-therapeutic levels may occur. No specific drug interaction data are available. Pregnancy and lactation: Safety in pregnancy and breast-feeding mothers not established. Caution when used as monotherapy for known or suspected *Pseudomonas aeruginosa* lower respiratory tract infection, regular sensitivity testing is recommended.

**Side Effects**

Meropenem is generally well tolerated. Local injection site reactions. Rash, pruritus, urticaria, abdominal pain, nausea, vomiting, diarrhoea, pseudomembranous colitis. Rarely erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis. Headache, paraesthesia and infrequently convulsions (although no causal relationship has been established). Oral and vaginal candidosis. Reversible thrombocytopenia, leucopenia, eosinophilia, thrombocytopenia and neutropenia (including rare cases of agranulocytosis). Positive Coombs test. Reduction in partial thromboplastin

Rarely systemic allergic reactions (hypersensitivity), which may include angioedema and manifestations of anaphylaxis.

**Overdosage**

Accidental overdosage could occur during therapy, particularly in patients with renal impairment. Treatment of overdosage should be symptomatic. In subjects with renal impairment haemodialysis will remove meropenem and its metabolite.

**Presentation**

Vials containing 500 mg or 1g meropenem blended with anhydrous sodium carbonate. Store below 30°C. Shake reconstituted solution before use. Do not freeze.

Meropenem is a trademark, the property of the AstraZeneca group of companies.

Further information is available on request. Consult the full prescribing information before prescribing.