Merocar IV Injection
Meropenem USP

Presentation
Merocar 500 mg injection: Each vial contains sterile Meropenem USP equivalent to 500 mg Meropenem.
Merocar 1 g injection: Each vial contains sterile Meropenem USP equivalent to 1 g Meropenem.

Pharmacology
Meropenem for injection is a sterile, pyrogen-free, synthetic, broad spectrum and carbapenem antibiotic for intravenous administration, more active against gram-negative bacilli. It has excellent penetration through bacterial cell wall with its high level of stability to all serine beta-lactamases and marked affinity for the Penicillin Binding Proteins (PBPs). The bactericidal activity of Meropenem results from the inhibition of cell wall synthesis. Meropenem has increased stability to degradation by human renal proximal tubule dehydropeptidase-I (DHP-I), therefore does not require the addition of an inhibitor of DHP-1.

Indication
Merocar is indicated for treatment in adults and children of the following infections caused by single or multiple susceptible bacteria and as empiric therapy prior to the identification of the causative organisms;

- Hospital and community acquired lower respiratory tract infections (pneumonia and nosocomial pneumonias)
- Urinary tract infections, including complicated infections
- Intra-abdominal infections
- Gynaecological infections, including postpartum infections
- Skin and skin structure infections
- Meningitis
- Septicaemia
- Cystic fibrosis
- Empiric treatment, including initial monotherapy, for presumed bacterial infections in host-compromised, neutropenic patients

Because of its broad spectrum of bactericidal activity against Gram-positive and Gram-negative aerobic and anaerobic bacteria, **Merocar** is effective for the treatment of polymicrobial infections.

Dosage and administration
Adults: Merocar is administered by IV injection or IV infusion. The dosage range is 1.5 gm-6 gm. The dosage and duration of therapy should be determined by the susceptibility of the causative organisms, the severity of infections and renal function of the patients. The recommended daily dosage is as follows:

Condition	Dose	Frequency
Pneumonia, UTI, Gynaecological infections such as Endometritis, Skin and skin structure infections	500 mg IV	Every 8 hours
Nosocomial pneumonias, Peritonitis, Febrile episodes in neutropenic patients, Septicaemia	1 g IV	Every 8 hours
Meningitis, Cystic fibrosis	2 g	Every 8 hours

Children:
The safety and effectiveness of **Merocar** IV injection have not been established less than 3 months of age.

3 months and up to 12 years of age: 10 to 40 mg/kg every 8 hours
Children over 50 kg weight: Adult dosage should be used
4 years to 18 years with cystic fibrosis: 25 to 40 mg/kg every 8 hours
Intra-abdominal infections: 20 mg/kg (up to 1 gm) every 8 hours
Meningitis: 40 mg/kg every 8 hours

Recommended daily dosage with impaired renal functions

Creatinine Clearance (mL/min)	Dose (dependent on type of infection)	Frequency
≤ 51	Recommended dose (500 mg cSSSI and 1g Intra-abdominal)	Every 8 hours
26-50	Recommended dose	Every 12 hours
10-25	One-half recommended dose	Every 12 hours
< 10	One-half recommended dose	Every 24 hours

Use in adults with hepatic insufficiency: No dosage adjustment is necessary in patients with impaired hepatic metabolism.

Elderly:
No dosage adjustment is required for the elderly with normal renal function or creatinine clearance values above 50 mL/min.

Contraindication
Meropenem is contraindicated in patients who have demonstrated hypersensitivity to this product.

Side effect
It is well tolerated. Side effects are rare. Local IV injection site reaction, systemic allergic reaction, blisters or peeling skin, rash, urinary abdominal pain, dark urine, decrease urination, nausea, vomiting, constipation, diarrhea, pseudomembranous colitis, thrombocytopenia, eosinophilia, leucopenia has been reported.

Precaution
Patients who have a history of hypersensitivity to carbapenem, penicillins or other beta-lactam antibiotics may also be hypersensitive to Meropenem. As with all beta-lactam antibiotics, rare hypersensitivity reactions have been reported. Prolonged use of Meropenem with other beta-lactam antibiotics may result in overgrowth of nonsusceptible organisms and therefore repeated evaluation of the patients is essential. Meropenem uses in patients with renal insufficiency, dosage adjustments are necessary.

Use in pregnancy & lactation
Although animal studies have not shown an adverse effect on the developing fetus. **Merocar** should be used in pregnancy unless the potential benefit justifies the potential risk to the fetus
Meropenem is detectable at very low concentrations in animal breast milk. Meropenem should not be used during breast-feeding unless potential benefit justifies the potential risk to the fetus.

Direction of reconstitution
For intravenous injection, constitute **Merocar** injection vials (500 mg and 1g) with sterile Water for Injection. (See table below)

Vial size	Amount of Diluent Added (ml)	Approximate Concentration (mg/ml)
500 mg	10	50
1 g	20	50

The vial should be shaken well and allow to stand until the solution is clear.
For intravenous infusion, vials (500 mg and 1g) should be diluted in a compatible IV solution.

Rate of administration
IV injections of Meropenem should be given over a 3-5 minutes period.
IV infusions of Meropenem should be given approximately 15-30 minutes.

Drug interaction
As the protein binding is so low (approx. 2%) that no interaction with other compounds would be expected on the basis of this mechanism. So, Meropenem has been administered concomitantly with many other medications without apparent adverse interaction. It may be reduced the serum level of valproic acid.

Overdosage
Treatment of overdosage should be symptomatic. If overdosing could occur during therapy particular in patients with renal impairment, haemodialysis will remove Meropenem and its metabolite.

Storage
Store it in cool and dry place. It is recommended to use freshly prepared **Merocar** for injection. Once reconstituted, solution may be stored up to 2 hrs at 15-25°C or up to 12 hrs at 4°C

Commercial pack
Merocar 500 mg IV injection: Each pack contains one vial of Meropenem 500 mg USP accompanied by one ampoule of 10 ml water for injection BP with a 10 ml sterile disposable syringe and a set of butterfly needle with an alcohol swab.

Merocar 1 gm IV injection: Each pack contains one vial of Meropenem 1gm USP accompanied by two ampoules of 10 ml water for injection BP with a 20 ml sterile disposable syringe and a set of butterfly needle with an alcohol swab.

Manufactured by
Globe Pharmaceuticals Ltd.
Noakhali, Bangladesh.