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

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# Meropenem & Tazobactam for Injection 1.125 g

## Icubac® T 1.125 g

आईसीयूबैक टी 1.125 ग्रा

**Composition:**
Each vial contains:
Meropenem (Sterile) IP
Eq. to Anhydrous Meropenem 1000 mg
(A Sterile Mixture of Meropenem IP &
Sodium Carbonate IP)
Tazobactam Sodium (Sterile) IP
Eq. to Anhydrous Tazobactam 125 mg

**DOSAGE FORM:** Powder for injection.

**INDICATIONS & USAGE:**
**Lower Respiratory Tract Infections**
Complicated lower respiratory tract infections caused by gram-negative bacteria.

**Skin and Skin Structure Infections**
Complicated skin and skin structure infections due to *Staphylococcus aureus (*methicillin susceptible isolates only), *Streptococcus pyogenes, Streptococcus agalactiae,* viridans group *streptococci, Enterococcus faecalis* (vancomycin-susceptible isolates only), *Pseudomonas aeruginosa, Escherichia coli, Proteus mirabilis, Bacteroides fragilis,* and *Peptostreptococcus* species.

**Intra-abdominal Infections**
Complicated appendicitis and peritonitis caused by viridans group *streptococci, Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Bacteroides fragilis, B. thetaiotaomicron,* and *Peptostreptococcus* species.

**Bacterial Meningitis**
Bacterial meningitis caused by *Streptococcus pneumoniae*, *Haemophilus influenzae* and *Neisseria meningitidis*.

**DOSAGE AND ADMINISTRATION:**
Meropenem & Tazobactam Injection every 8 hours by intravenous infusion over 15 to 30 minutes for adult patients. It can also be given every 8 hours by intravenous bolus injection (5 to 20 mL) over 3 to 5 minutes for adult patients.

**For Infusion:** Infusion vials may be directly constituted with a compatible infusion fluid. Alternatively, an injection vial may be constituted, then the resulting solution added to an I.V. container and further diluted with an appropriate infusion fluid.

**CONTRAINDICATIONS:**
Meropenem & Tazobactam for Injection 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 beta-lactams.

**WARNINGS AND PRECAUTIONS**

**Hypersensitivity Reactions**
Serious and occasionally fatal hypersensitivity reactions have been reported in patients receiving therapy with β-lactams. These reactions are more likely to occur in individuals with a history of sensitivity to multiple allergens. Before initiating therapy with Meropenem and Tazobactam Injection, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, other β-lactams, and other allergens. If an allergic reaction occurs, discontinue the drug immediately.

**Seizure Potential**
Seizures and other adverse CNS side effects may occur during treatment with Meropenem-Tazobactam These experiences have occurred most commonly in patients with CNS disorders (e.g. brain lesions or history of seizeres) or with bacterial meningitis and/or compromised renal functions.

**Development of Drug-Resistant Bacteria**
Prescribing Meropenem & Tazobactam in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

**Patients with Renal Impairment**
In patients with renal dysfunction, thrombocytopenia has been observed but no clinical bleeding reported. Dosage adjustment is recommended in patients with advanced age and/or reduced renal function.

**Dialysis**
There is inadequate information regarding the use of Meropenem-Tazobactam injection in patients on hemodialysis or peritoneal dialysis.

**ADVERSE REACTIONS:**
**Local Adverse Reactions:** Inflammation at the injection site, Phiebitis/ thrombophlebitis, Pain at the injection site, Edema at the injection side.
**Systemic Allergic Reactions:** Rarely systemic allergic reactions or hypersensitivity may occur following the administration of Meropenem. These reactions may include angio-oedema and manifestations of anaphylaxis.
**Body as a Whole:** Pain, abdominal pain, chest pain, fever, back pain, abdominal enlargement, chills, pelvic pain.
Cardiovascular: Heart Failure, Heart arrest, Techycardia, Hypertension, Myocardial Infarction, Pulmonary ombolus, bradycardia, Hypotension and synocope.
**Degestive System:** Oral Moniliasis, Anorexia, Cholestatic Jaundice, Flatulence, ileus, Hepatic failure, Dyspepsia, intestinal obstruction.
**Respiratory:** Respiratory disorder, dyspnea, pleural effusion, asthma, lung edema.
**Skin:** Urticaria, Sweating and skin ulcer.

**Pregnancy:**
**Pregnancy Category B:** There are no adequate and well-controlled studies in pregnant women, Meropenem & Tazobactam for Injection should not be used in pregnancy unless the potential benefit justifies the potential risk to the foetus.
**Lactation:** Meropenem is detectable at very low concentrations in animal breast milk. It should not be used in nursing mothers unless the potential benefit justifies the potential risk to the baby.
**Geriatric Use:** Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

**DRUG INTERACTIONS:**
**Probenecid**
Probenecid competes with Meropenem for active tubular secretion, resulting in increased plasma concentrations of Meropenem. Co-administration of probenecid with Meropenem is not recommended.
**Valproic Acid**
Case reports in the literature have shown that co-administration of carbapenems, including Meropenem, to patients receiving valproic acid or devalproex sodium results in a reduction in valproic acid concentrations. The Valproic Acid concontrations may drop below the therapeutic range as a result of this interaction, therefore increasing the risk of breakthrough seizures.

**USE IN SPECIFIC POPULATIONS**
**Pregnancy**
Meropenem is under pregnancy category B. There are not adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.
**Lactation**
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Meropenem IV is administered to a nursing women.

**OVER DOSAGE:**
The largest dose of Meropenem & Tazobactam for Injection administered in clinical trials has been 2 gm given intravenously every 8 hours. At the dosage, no adverse pharmacological effects or increased safety risks have been observed.

**PHARMACOKINETIC AND PHARMACODYNAMIC PROPERTIES:**
**Pharmacodynamics:**
Meropenem is a broad-spectrum carbapenem antibiotic. The bactericidal activity of Meropenem results from the inhibition of cell wall synthesis. Meropenem readily penetrates the cell wall of most Gram-positive and Gram-negative bacteria to reach penicillin-binding-protein (PBP) targets. Its strongest affinities are toward PBPs 2, 3 and 4 of Escherichia coli and Pseudomonas aeruginosa and PBPs 1, 2 and 4 of Staphylococcus aureus. Meropenem has significant stability to hydrolysis by betalactamases, both penicillinases and cephalosporinases produced by Gram-positive and Gram-negative bacteria.
The Tazobactam extends the antibiotic spectrum of Meropenem against beta-lactamase and extended spectrum beta lactamase (ESBL) producing bacteria. Thus, Meropenem & Tazobactam for Injection possesses most potent activity against hospital acquired serious infections caused by ESBLs.
**Pharmacokinetic:**
At the end of a 30 minutes IV infusion of a single dose of Meropenem in healthy volunteers, mean peak plasma concentrations are approximately 49 mcg/ml. (range: 39-58) for the 1g dose. A 5 minutes IV bolus injection of Meropenem in healthy volunteers results in mean peak plasma concentration of approximately 112 mcg/ml. (range 83 to 140) for the 1g dose. No accumulation of Meropenem in plasma was observed with dose 1g administered every 6 hours in healthy volunteers with normal renal function.
Meropenem penetrates well into most body fluids and tissues, including the cerebrospinal fluid, achieving concentrations matching or exceeding those required to inhibit most susceptible bacteria. The Plasma protein binding of Meropenem is approximately 2%.
In subjects with normal renal function, the elimination half-life of Meropenem approximately 1 hour. Approximately 70% of the dose is excreted unchanged with12 hours.
Bioavailability of Tazobactam after IV administration is same as after IM dosage. Tazobactam is widely distributed into the tissues. Mean serum half life Tazobactam is 3.44+/-0.94 hr. Approximately 75 to 85% of Meropenem Tazobactam is excreted unchanged in the urine during the first 8 hour after administration. About 38% of Tazobactam is reversibly bound to human serum protein. Tazobactam has greater volume of distribution than clavulanic acid and tazobactam.

**COMPATIBILITY :** Meropenem & Tazobactam for Injection should not be mixed with or physiologically added to solution containing other drugs.

**Storage : Store in a cool & dry place below 25°C, protect from light & moisture.**

Keep the Medicine out of reach of children

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