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

MEROPENEM INJECTION IP 125/250/500/1000 mg

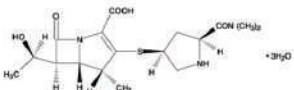
1. COMPOSITION :
Each Vial contains:
Meropenem Trihydrate (Sterile) I.P.
Eq. to Meropenem Anhydrous 1000 mg
Sodium Carbonate eq. To Sodium
90.2 mg (as buffer)

2. COMPOSITION :
Each Vial contains:
Meropenem Trihydrate (Sterile) I.P.
Eq. to Meropenem Anhydrous 500 mg
Sodium Carbonate eq. To Sodium
45.1 mg (as buffer)

3. COMPOSITION :
Each Vial contains:
Meropenem Trihydrate (Sterile) I.P.
Eq. to Meropenem Anhydrous 250 mg
Sodium Carbonate eq. To Sodium
22.55 mg (as buffer)

2. COMPOSITION :
Each Vial contains:
Meropenem Trihydrate (Sterile) I.P.
Eq. to Meropenem Anhydrous 125 mg
Sodium Carbonate eq. To Sodium
11.27 mg (as buffer)

DESCRIPTION :
Meropenem for Injection is a sterile, pyrogen-free, synthetic, broad-spectrum, carbapenem antibiotic for intravenous administration. It is (4R,5S,6S)-3-[[(3S,5S)-5-(Dimethylcarbamoyl)-3-pyrrolidinyl]thio]-6- [(1R)-1-hydroxyethyl]-4-methyl-7-oxo-1-azabicyclo[3.2.0]hept-2-ene-2-carboxylic acid Trihydrate. Its empirical formula is $C_{17}H_{25}N_3O_5S_3H_2O$ with a molecular weight of 437.52. Its structural formula is:



Meropenem for Injection is a white to off white crystalline powder. The solution varies from colorless to yellow depending on the concentration. The pH of freshly constituted solutions is between 7.3 and 8.3. Meropenem is soluble in 5% monobasic potassium phosphate solution, sparingly soluble in water, very slightly soluble in hydrated ethanol, and practically insoluble in acetone or ether.
When constituted as instructed, each 1 g Meropenem for Injection vial will deliver 1 g of Meropenem and 90.2 mg of sodium as sodium carbonate (3.92 mEq). Each 500 mg Meropenem for Injection vial will deliver 500 mg Meropenem and 45.1 mg of sodium as sodium carbonate. Each 250 mg Meropenem for Injection vial will deliver 250 mg Meropenem and 22.55 mg of sodium as sodium carbonate. Each 125 mg Meropenem for Injection vial will deliver 125 mg Meropenem and 11.275 mg of sodium as sodium carbonate.
Administration : Meropenem must be administered intravenously. It is supplied as a white crystalline powder to be dissolved in 5% monobasic potassium phosphate solution. Dosing must be adjusted for altered kidney function and for haemofiltration.

CLINICAL PHARMACOLOGY :
Mechanism of Action : Meropenem is an antibacterial drug.
Pharmacokinetics:
Plasma Concentrations : At the end of a 30-minute intravenous infusion of a single dose of Meropenem for Injection in healthy volunteers, mean peak plasma concentrations of Meropenem are approximately 23 mcg/mL (range 14 to 26) for the 500 mg dose and 49 mcg/mL (range 39 to 58) for the 1 g dose. A 5-minute intravenous bolus injection of Meropenem for Injection in healthy volunteers results in mean peak plasma concentrations of approximately 45 mcg/mL (range 18 to 85) for the 500 mg dose and 112 mcg/mL (range 83 to 140) for the 1 g dose. Following intravenous doses of 500 mg, mean plasma concentrations of Meropenem usually decline to approximately 1 mcg/mL at 6 hours after administration. No accumulation of Meropenem in plasma was observed with regimens using 500 mg administered every 8 hours or 1 g administered every 6 hours in healthy volunteers with normal renal function.
Distribution : The plasma protein binding of Meropenem is approximately 2%. Meropenem penetrates well into most body fluids and tissues including cerebrospinal fluid, achieving concentrations matching or exceeding those required to inhibit most susceptible bacteria. After a single intravenous dose of Meropenem for Injection, the highest mean concentrations of Meropenem were found in tissues and fluids at 1 hour (0.5 to 1.5 hours) after the start of infusion.

INDICATIONS AND USAGE :
To reduce the development of drug-resistant bacteria and maintain the effectiveness of Meropenem for Injection and other antibacterial drugs, Meropenem for Injection 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. Meropenem for Injection is useful as presumptive therapy in the indicated condition (e.g., intra-abdominal infections) prior to the identification of the causative organisms because of its broad spectrum of bactericidal activity.
Skin and Skin Structure Infections (Adult Patients and Pediatric Patients ≥3 Months only)
Meropenem for Injection is indicated as a single agent therapy for the treatment of complicated skin and skin structure infections due to *Staphylococcus aureus* (β-lactamases- and non-β-lactamases-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 (Adult Patients and Pediatric Patients ≥ 3 Months only)**
Meropenem for Injection is indicated as a single agent therapy for the treatment of complicated appendicitis and peritonitis caused by viridans group streptococci, *Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Bacteroides fragilis, B. thetaiotaomicron,* and *Peptostreptococcus* species.
Bacterial Meningitis (Pediatric Patients ≥3 Months only)
Meropenem for Injection is indicated as a single agent therapy for the treatment of bacterial meningitis caused by *Streptococcus pneumoniae*‡, *Haemophilus influenzae* (β-lactamases- and non-β-lactamases-producing isolates), and *Neisseria meningitides.*
‡ The efficacy of Meropenem as monotherapy in the treatment of meningitis caused by penicillin nonsusceptible isolates of *Streptococcus pneumoniae* has not been established.

DOSAGE AND ADMINISTRATION :
Adult Patients : The recommended dose of Meropenem for Injection is 500 mg given every 8 hours for skin and skin structure infections and 1 g given every 8 hours for intra-abdominal infections. Meropenem for Injection 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 to 5 minutes.
Use in Adult Patients with Renal Impairment
Dosage should be reduced in patients with creatinine clearance of 50 mL/min or less.
Use in Pediatric Patients (>3 Months only)
For pediatric patients from 3 months of age and older, the Meropenem for Injection 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). Pediatric patients weighing over 50 kg should be administered Meropenem for Injection 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. Meropenem for Injection 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 to 5 minutes. There is no experience in pediatric patients with renal impairment.
Preparation of Solution
Intravenous Bolus Administration
Constitute injection vials (125 mg, 250 mg ,500 mg and 1 g) with sterile Water for Injection. Shake to dissolve and let stand until clear.
For Infusion
Infusion vials (125 mg, 250 mg, 500 mg and 1 g) 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

WARNING:
Do not use flexible container in series connections.
Compatibility
Compatibility of Meropenem with other drugs has not been established. Meropenem should not be mixed with or physically added to solutions containing other drugs.

CONTRAINDICATIONS :
Meropenem 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 β-lactams.
Hypersensitivity Reactions : Serious and occasionally fatal hypersensitivity (anaphylactic) 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. There have been reports of individuals with a history of penicillin hypersensitivity who have experienced severe hypersensitivity reactions when treated with another β-lactam. Before initiating therapy with Meropenem for Injection, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, other β-lactam, and other allergens. If an allergic reaction to Meropenem for Injection 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.
Seizure Potential : Seizures and other adverse CNS experiences have been reported during treatment with Meropenem for Injection These experiences have occurred most commonly in patients with CNS disorders (e.g., brain lesions or history of seizures) or with bacterial meningitis and/or compromised renal function. Close adherence to the recommended dosage regimens is urged, especially in patients with known factors that predispose to convulsive activity. Anti-convulsant therapy should be continued in patients with known seizure disorders. If focal tremors, myoclonus, or seizures occur, patients should be evaluated neurologically, placed on anti-convulsant therapy if not already instituted, and the dosage of Meropenem for Injection re-examined to determine whether it should be decreased or the antibiotic discontinued.
Interaction with Valproic Acid : Case reports in the literature have shown that co-administration of carbapenems, including Meropenem, to patients receiving valproic acid or divalproex sodium results in a reduction in valproic acid concentrations. The valproic acid concentrations may drop below the therapeutic range as a result of this interaction, therefore increasing the risk of breakthrough seizures. Increasing the dose of valproic acid or divalproex sodium may not be sufficient to overcome this interaction. The concomitant use of Meropenem and valproic acid or divalproex sodium is generally not recommended. Antibacterial other than carbapenems should be considered to treat infections in patients whose seizures are well controlled on valproic acid or divalproex sodium. If administration of Meropenem for Injection is necessary, supplemental anti-convulsant therapy should be considered.
Clostridium difficile–Associated Diarrhea : *Clostridium difficile*- associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Meropenem for Injection, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*. *C. difficile* produces toxins A and B which contribute to the development of CDAD. Hyper toxin producing isolates of *C.difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.
If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.
Development of Drug-Resistant Bacteria : Prescribing Meropenem for Injection 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.
Overgrowth of Nonsusceptible Organisms : As with other broad-spectrum antibiotics, prolonged use of Meropenem may result in overgrowth of nonsusceptible organisms. Repeated evaluation of the patient is essential. If super infection does occur during therapy, appropriate measures should be taken.
Patients with Renal Impairment : In patients with renal impairment, thrombocytopenia has been observed but no clinical bleeding reported.
Dialysis : There is inadequate information regarding the use of Meropenem for Injection in patients on hemodialysis or peritoneal dialysis.
Adverse Reactions from Clinical Trials : Because clinical trials are conducted under widely varying conditions, adverse reactions rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.
Adult Patients: During clinical investigations, 2904 immunocompetent adult patients were treated for non-CNS infections with Meropenem for Injection (500 mg or 1000 mg every 8 hours). Deaths in 5 patients were assessed as possibly related to Meropenem; 36 (1.2%) patients had Meropenem discontinued because of adverse events. Many patients in these trials were severely ill and had multiple background diseases, physiological impairments and were receiving multiple other drug therapies. In the seriously ill patient population, it was not possible to determine the relationship between observed adverse events and therapy with Meropenem for Injection. The following adverse reaction frequencies were derived from the clinical trials in the 2904 patients treated with Meropenem for Injection
Systemic Adverse Reactions : Systemic adverse reactions that were reported irrespective of the relationship to Meropenem for Injection occurring in greater than 1% of the patients were diarrhea (4.8%), nausea/vomiting (3.6%), headache (2.3%), rash (1.9%), sepsis (1.6%), constipation (1.4%), apnea (1.3%), shock (1.2%), and pruritus (1.2%).
Additional systemic adverse reactions that were reported irrespective of relationship to therapy with Meropenem for Injection and occurring in less than or equal to 1% but greater than 0.1% of the patients are listed below within each body system in order of decreasing frequency:
Bleeding events were seen as follows: gastrointestinal hemorrhage (0.5%), melena (0.3%), epistaxis (0.2%), hemoperitoneum (0.2%), summing to 1.2%.
Body as a Whole: pain, abdominal pain, chest pain, fever, back pain, abdominal enlargement, chills, pelvic pain
Cardiovascular: heart failure, heart arrest, tachycardia, hypertension, myocardial infarction, pulmonary embolus, bradycardia, hypotension, syncope
Digestive System: oral moniliasis, anorexia, cholestatic jaundice/jaundice, flatulence, ileus, hepatic failure, dyspepsia, intestinal obstruction
Hemic/Lymphatic: anemia, hypochromic anemia, hypervolemia
Metabolic/Nutritional: peripheral edema, hypoxia
Nervous System: insomnia, agitation/delirium, confusion, dizziness, seizure, nervousness, paresthesia, hallucinations, somnolence, anxiety, depression, asthenia **Respiratory:** respiratory disorder, dyspnea, pleural effusion, asthma, cough increased, lung edema
Skin and Appendages: urticaria, sweating, skin ulcer
Urogenital System: dysuria, kidney failure, vaginal moniliasis, urinary incontinence
Adverse Laboratory Changes
Adverse laboratory changes that were reported irrespective of relationship to Meropenem for Injection and occurring in greater than 0.2% of the patients were as follows:
Hepatic: increased SGPT (ALT), SGOT (AST), alkaline phosphatase, LDH, and bilirubin
Hematologic: increased platelets, increased eosinophils, decreased platelets, decreased hemoglobin, decreased hematocrit, decreased WBC, shortened prothrombin time and shortened partial thromboplastin time, leukocytosis, hypokalemia
Renal: increased creatinine and increased BUN
NOTE: For patients with varying degrees of renal impairment, the incidence of heart failure, kidney failure, seizure and shock reported irrespective of relationship to Meropenem for Injection, increased in patients with moderately severe renal impairment (creatinine clearance >10 to 26 mL/min).
Urinalysis: presence of red blood cells

NONCLINICAL TOXICOLOGY :
Carcinogenesis : Carcinogenesis studies have not been performed.
Mutagenesis : Genetic toxicity studies were performed with Meropenem using the bacterial reverse mutation test, the Chinese hamster ovary HGPRT assay, cultured human lymphocytes cytogenic assay, and the mouse micronucleus test. There was no evidence of mutagenic potential found in any of these tests.
Impairment of Fertility : Reproductive studies were performed with meropenem in rats at doses up to 1000 mg/kg/day, and cynomolgus monkeys at doses up to 360 mg/kg/day (on the basis of AUC comparisons, approximately 1.8 times and 3.7 times, respectively, to the human exposure at the usual dose of 1 g every 8 hours). There was no reproductive toxicity seen.

CLINICAL STUDIES
Complicated Skin and Skin Structure Infections : Adult patients with complicated skin and skin structure infections including complicated cellulitis, complex abscesses, perirectal abscesses, and skin infections requiring intravenous antimicrobials, hospitalization, and surgical intervention were enrolled in a randomized, multi-center, international, double-blind trial. The study evaluated meropenem at doses of 500 mg administered intravenously every 8 hours and imipenem-cilastatin at doses of 500 mg administered intravenously every 8 hours. The study compared the clinical response between treatment groups in the clinically evaluable population at the follow-up visit (test-of-cure). The trial was conducted in the United States, South Africa, Canada, and Brazil. At enrollment, approximately 37% of the patients had underlying diabetes, 12% had underlying peripheral vascular disease and 67% had a surgical intervention. The study included 510 patients randomized to meropenem and 527 patients randomized to imipenem-cilastatin. Two hundred and sixty one (261) patients randomized to meropenem and 287 patients randomized to imipenem-cilastatin were clinically evaluable. The success rates in the clinically evaluable patients at the follow-up visit were 86% (225/261) in the meropenem arm and 83% (238/287) in imipenem-cilastatin arm.
Complicated Intra-Abdominal Infections : One controlled clinical study of complicated intra-abdominal infection was performed in the United States where meropenem was compared with clindamycin/tobramycin. Three controlled clinical studies of complicated intra-abdominal infections were performed in Europe; meropenem was compared with imipenem (two trials) and cefotaxime/metronidazole (one trial).
Using strict evaluability criteria and microbiologic eradication and clinical cures at follow-up which occurred 7 or more days after completion of therapy, the following presumptive microbiologic eradication/clinical cure rates and statistical findings were obtained:
The finding that meropenem was not statistically equivalent to cefotaxime/metronidazole may have been due to uneven assignment of more seriously ill patients to the meropenem arm. Currently there is no additional information available to further interpret this observation.
Bacterial Meningitis : Four hundred forty-six patients (397 pediatric patients ≥ 3 months to < 17 years of age) were enrolled in 4 separate clinical trials and randomized to treatment with meropenem (n=225) at a dose of 40 mg/kg every 8 hours or a comparator drug, i.e., cefotaxime (n=187) or ceftriaxone (n=34), at the approved dosing regimens. A comparable number of patients were found to be clinically evaluable (ranging from 61 to 68%) and with a similar distribution of pathogens isolated on initial CSF culture.
Patients were defined as clinically not cured if any one of the following three criteria were met:
1. At the 5 to 7 week post-completion of therapy visit, the patient had any one of the following: moderate to severe motor, behavior or development deficits, hearing loss of >60 decibels in one or both ears, or blindness.
2. During therapy the patient's clinical status necessitated the addition of other antibiotics.
3. Either during or post-therapy, the patient developed a large subdural effusion needing surgical drainage, or a cerebral abscess, or a bacteriologic relapse.

STABILITY AND STORAGE
Freshly prepared solutions of Meropenem should be used whenever possible. However, constituted solutions of Meropenem maintain satisfactory potency at controlled room temperature 15-25°C (59-77°F) or under refrigeration at 4°C (39°F) as described below. Solutions of intravenous Meropenem should not be frozen.
Intravenous Bolus Administration : Meropenem for injection vials constituted with sterile Water for Injection for bolus administration (up to 50 mg/mL of Meropenem) may be stored for up to 2 hours at controlled room temperature 15-25°C (59-77°F) or for up to 12 hours at 4°C (39°F).
Intravenous Infusion Administration : Stability in Infusion Vials: Meropenem for injection infusion vials constituted with Sodium Chloride Injection 0.9% (Meropenem concentrations ranging from 2.5 to 50 mg/mL) are stable for up to 2 hours at controlled room temperature 15-25°C (59-77°F) or for up to 18 hours at 4°C (39°F). Infusion vials of Meropenem for Injection constituted with Dextrose Injection 5% (Meropenem concentrations ranging from 2.5 to 50 mg/mL) are stable for up to 1 hour at controlled room temperature 15-25°C (59-77°F) or for up to 8 hours at 4°C (39°F).

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 divalproex sodium results in a reduction in valproic acid concentrations. The valproic acid concentrations may drop below the therapeutic range as a result of this interaction, therefore increasing the risk of breakthrough seizures. Although the mechanism of this interaction is unknown, data from *in vitro* and animal studies suggest that carbapenems may inhibit the hydrolysis of valproic acid's glucuronide metabolite (VPA-g) back to valproic acid, thus decreasing the serum concentrations of valproic acid. If administration of Meropenem for Injection is necessary, then supplemental anti-convulsant therapy should be considered

USE IN SPECIFIC POPULATIONS
Pregnancy : Pregnancy Category B
Reproductive studies have been performed with meropenem in rats at doses of up to 1000 mg/kg/day, and cynomolgus monkeys at doses of up to 360 mg/kg/day (on the basis of AUC comparisons, approximately 1.8 times and 3.7 times, respectively, to the human exposure at the usual dose of 1 g every 8 hours). These studies revealed no evidence of impaired fertility or harm to the fetus due to meropenem, although there were slight changes in fetal body weight at doses of 250 mg/kg/day (on the basis of AUC comparisons, 0.4 times the human exposure at a dose of 1 g every 8 hours) and above in rats. There are, however, no 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.
Nursing Mothers : 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 using meropenam.
Pediatric Use : The safety and effectiveness of Meropenem for Injection have been established for pediatric patients ≥3 months of age. Use of Meropenem for Injection in pediatric patients with bacterial meningitis is supported by evidence from adequate and well-controlled studies in the pediatric population. Use of Meropenem for Injection in pediatric patients with intra-abdominal infections is supported by evidence from adequate and well-controlled studies with adults with additional data from pediatric pharmacokinetics studies and controlled clinical trials in pediatric patients. Use of Meropenem for Injection in pediatric patients with complicated skin and skin structure infections is supported by evidence from an adequate and well-controlled study with adults and additional data from pediatric pharmacokinetics studies.
Geriatric Use : Of the total number of subjects in clinical studies of Meropenem for Injection, approximately 1100 (30%) were 65 years of age and older, while 400 (11%) were 75 years and older. Additionally, in a study of 511 patients with complicated skin and skin structure infections, 93 (18%) were 65 years of age and older, while 38 (7%) were 75 years and older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects; spontaneous reports and other reported clinical experience have not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

OVERDOSAGE :
In mice and rats, large intravenous doses of Meropenem (2200-4000 mg/kg) have been associated with ataxia, dyspnea, convulsions, and mortalities.
Intentional overdosing of Meropenem for Injection is unlikely, although accidental overdosing might occur if large doses are given to patients with reduced renal function. The largest dose of Meropenem administered in clinical trials has been 2 g given intravenously every 8 hours. At this dosage, no adverse pharmacological effects or increased safety risks have been observed.
Limited post-marketing experience indicates that if adverse events occur following over dosage, they are consistent with the adverse event profile described in the Adverse Reactions section and are generally mild in severity and resolve on withdrawal or dose reduction. Symptomatic treatments should be considered. In individuals with normal renal function, rapid renal elimination takes place. Meropenem and its metabolite are readily dialyzable and effectively removed by hemodialysis; however, no information is available on the use of hemodialysis to treat over dosage.

SUPPLY/STORAGE AND HANDLING :
Meropenem for Injection is supplied in vials containing sufficient Meropenem to deliver 125 mg, 250 mg, 500 mg, 1 g or 2 g for intravenous administration, respectively. The dry powder should be stored below 25°C. Protect from moisture. Do not freeze.

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