EXIPENEM® 1g

Meropenem

Description

Meropenem is a synthetic carbapenem antibiotic structurally and pharmacologically related to other carbapenems (e.g., imipenem, ertapenem).

Ingredients:

It contains Meropenem (as trihydrate) as active ingredient, Sodium Carbonate as excipient. (1)

Clinical pharmacology

Meropenem inhibits cell wall synthesis by penetrating the cell wall of most gram-positive and gram-negative bacteria to reach penicillin-binding-protein (PBP) targets. Its strongest affinity is toward PBPs 2, 3 and 4 of Escherichia coli and Pseudomonas aeroginosa, and PBPs 1, 2, and 4 of Staphylococcus aureus.Bactericidal concentration are typically one to two times the bacteriostatic concentration; the exception is Listeria monocytogenes, against which lethal activity has not been observed. (3)

Pharmacokinetics

Half-life	1 hour
Metabolism	Hepatic
Excretion	Urine (2)

Indication

1.Intra-abdominal Infections

Meropenem is used for the treatment of intra-abdominal infections, including complicated appendicitis and peritonitis, caused by susceptible bacteria. The drug may be used as monotherapy for the treatment of intra-abdominal infections caused by susceptible viridians streptococci, Escherichia coli, Klebsilla pneumonia, Pseudomonas aeruginosa, Bacteroides fragilis, B. thetaiotaomicron, or Peptostreptococcus. Because meropenem has a broad spectrum of antibacterial activity, the drug may be used empirically to treat intra-abdominal infections before identification of the causative organism.

2.Meningitis

Meropenem is used for the treatment of bacterial meningitis caused by susceptible Steptococcus pneumoniae, Haemophilus influenzae (including β-lactamase-producting strains), or Neisseria meningitidis in children 3 months of age and older. The drug also is used in the treatment of meningitis in adults. Efficacy of meropenem for the treatment of meningitis caused by highly penicillin- or cephalosporin-resistant S. pneumoniae has not been established.

3.Respiratory Tract Infections

Meropenem is used in the treatment of respiratory tract infections. Including community-acquired pneumoniae (CAP) and nosocomical pneumoniae, caused by susceptible bacteria.

4.Septicemia

Meropenem has been used for the treatment of septicemia caused by susceptible bacteria. There is evidence that concurrent bacteremia associated with bacterial meningitis has been eliminated during meropenem meningitis treatment.

5.Skin and Skin Structure Infections

Meropenem is used for the treatment of complicated skin and skin structure infections caused by susceptible Staphylococcus aureus (including β-lactamase-producting strains, but not oxacillin-resistant [methicillin-resistant] strains), S. pyogenes (group A β-hemolytic streptococci), S. agalactiae (group B streptococci), viridans streptococci, Enterococcus faecalis (except vancomycin-resistant strains), Ps. aeruginosa, E. coli, Proteus mirabilis, B. fragilis, or Peptostreptococcus.

6.Urinary Tract Infections

Although safety and efficacy have not been established, meropenem has been used for the treatment of complicated urinary tract infections caused by susceptible bacteria. Some clinicians suggest that urinary tract infections is hospitalized patients should be treated with a third generation cephalosporin, a fluoroquinolon, fixed combination of piperacillin and tazobactam, imipenem, or meropenem; an aminoglycoside should be used concomitantly, especially in patients with sepsis.

7.Empiric Therapy in Febrile Neutropenic Patients

Meropenem is used alone or in conjunction with other anti-infectives for empiric anti-infective therapy of presumed bacterial infections in febrile neutropenic patients. (1)

Contraindication

Known hypersensitivity to meropenem, other carbapenems, or any ingredient in the formulation. History of anaphylactic reaction to β-lactams. (1)

Precaution

Serious hypersensitivity reactions, including anaphylaxis, have been reported (some without a history of previous allergic reactions to beta-lactamas). Has been associated with CNS adverse effects, including confusional states and seizures; use caution with CNS disorders (eg, brain lesion history of seizures, or renal impairment). Prolonged use may result in fungal or bacterial superinfection, including C.difficile-associated diarrhea (CDAD) and pseudomemberanus colitis; CDAD has been observed > 2 months postantibiotic treatment. Use with caution in patients with renal impairment; dosage adjustment required in patients with moderate-to-severe renal dysfunction. Thrombocytopenia has been reported in patients with renal dysfunction. Lower doses (based upon renal function) are often required in the elderly.

Pregnancy

pregnancy category B

No evidence of impaired fertility or fetal harm has been found in animals. Adequate and well-controlled studies have not been conducted in pregnant women and it is not known whether meropenem can cause fetal harm.

Breast feeding

Excretion in breast milk is unknown. Use with caution. (2)

Dosage

Usual adult and adolescent dose

Antibacterial

Intravenous, 1 gram, administered by intravenous infusion over fifteen to thirty minutes or by rapid intravenous injection over three to five minutes, every eight hours.

Skin and skin structure infections, complicated (treatment)

Intravenous, 500 mg, administered by intravenous infusion over fifteen to thirty minutes or by rapid intravenous injection over three to five minutes, every 8 hours. Adult with impaired renal function may require a reduction in dose as given below.

Creatinine Clearance

(ml/min)/(ml/sec)
>51/0.85
26-50/0.43-0.83
10-25/0.17-0.42
<10/0.17

Dose

See usual adult and adolescent dose
1 gram every 12 hours
500 mg every 12 hours
500 mg every 24 hours

Neutropenia, febrile

Intravenous, 1 gram, administered by intravenous infusion over twenty to thirty minutes, every eight hours. Adult with impaired renal function may require a reduction in dose as given above.

Note: No dosage adjustment is necessary in patients with impaired hepatic function.

Usual pediatric prescribing dose

For complicated skin and skin structure infections: 500 mg every 8 hours

For intra-abdominal infections: 1 gram every 8 hours

For meningitis: 2 gram every eight hours. (3)

Administration

Administer I.V. infusion over 15-30 minutes; I.V. bolus injection over 3-5 minutes.

Patient consultation

Antibacterials (including meropenem) should only be used to treat bacterial infections and not used to treat viral infections (e.g, the common cold).

Importance of completing full course of therapy, even if feeling better after a few days.

Skipping dose or not completing the full course of therapy may decrease effectiveness and increase the likelihood that bacteria will develop resistance and will not be treatable with meropenem or other antibacterials in the future.

Importance of informing clinicians of other medical conditions, including history of seizures.

Importance of discontinuing therapy and informing clinician if an allergic or hypersensitivity reaction occurs.

Importance of informing clinicians of existing or contemplated concomitant therapy, including prescription and OTC drugs, and any concomitant illnesses.

Importance of women informing clinicians if they are or plan to become pregnant or plan to breast-feed. (1)

Warning

Possible emergence and overgrowth of nonsusceptible organism. Treatment with anti-infectives may permit overgrowth of clostridia.

Consider Clostridium difficile-associated diarrhea and colitis (antibiotic-associated pseudomembranous colitis).

seizures and other adverse CNS effects reported during meropenem therapy, do not exceed recommended dosage, especially in those with known factors that predispose to seizure.

If hypersensitivity occurs, discontinue meropenem.

Partial cross-allergenicity among β-lactam antibiotics,including penicillins, cephalosporins, and other β-lactams. (1)

Interaction

Aminoglycosides Potential pharmacologic interaction (synergistic antibacterial effects against Pseudomonas aeruginosa).

Probenecid Pharmacokinetic interaction (decreased renal tubular secretion of meropenem; increased systemic exposure and prolonged meropenem half-life). Concomitant use not recommended.

Valproic Acid Pharmacokinetic interaction (valproic acid serum concentrations may be decreased to subtherapeutic concentrations; possible increased risk of seizures). Use concomitantly with caution. (1)

Adverse reactions

Those indicating need for medical attention

Incidence more frequent

Inflammation at site of injection (redness and swelling at site of injection)

Incidence less frequent

Apnea (bluish lips or skin; not breathing); pruritus (itching skin); sepsis (chills; confusion; dizziness; lightheadedness; fainting; fast heart beat; fever; rapid, shallow breathing); shock (cold clammy skin; confusion; dizziness, lightheadedness; fast, weak pulse; sweating; wheezing); skin rash and itching; thrombophlebitis (pain at site of injection)

Those indicating need for medical attention only if they continue or are bothersome

Incidence more frequent

Anemia (pale skin; troubled breathing with exertion; unusual bleeding or bruising; unusual tiredness or weakness); gastrointestinal disturbances (constipation; diarrhea; nausea and vomiting); pain

Those indicating the need for medical attention if they occur after medication is discontinued

Pseudomembranous colitis (abdominal or stomach cramps and pain, severe; diarrhea, watery and severe, which may also be bloody; fever). (3)

Overdose

No cases of overdose have been reported in humans to date. The largest dose of meropenem administered in clinical trials has been 2 grams every 8 hours and no increased safety risks have been seen. (3)

Storage and stability condition

Befor reconstitution store below 30°C.

Protect from light.

Keep out of the reach of children.

DO NOT use the drug after the expiration date.

Use the solution after reconstitution immediately.(3)

Packaging

500 mg dry powder.
1000 mg dry powder. (3)

References

1.AHFS DRUG INFORMATION 2010

2.LEXI-COMP´S DRUG REFERENCE HAND BOOKS 2010-1011

3.Drug Information for the Health Care Professional (USPDI) 2007

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