Information For the Use Amoxycillin (500mg) + Clavulanic Acid (100mg)

Moxyplit CV 600 Injection

Amoxicillin (500mg) + Clavulanic Acid (100mg) Injection

Composition:

Each vial contains:

- Amoxicillin (as Amoxicillin Trihydrate) 500mg
- Clavulanic Acid (as Potassium Clavulanate) 100mg

Description:

Amoxicillin is a broad-spectrum antibiotic belonging to the penicillin class. It inhibits bacterial cell wall synthesis, leading to bacterial death. Clavulanic acid is a beta-lactamase inhibitor, which protects amoxicillin from degradation by beta-lactamase-producing bacteria, enhancing the spectrum of activity against resistant organisms.

Indications:

Amoxicillin + Clavulanic Acid injection is indicated for the treatment of infections caused by susceptible microorganisms, including:

- Respiratory Tract Infections: Pneumonia, acute otitis media, sinusitis, and bronchitis.
- Urinary Tract Infections: Cystitis, pyelonephritis, and other urinary tract infections.
- Skin and Soft Tissue Infections: Cellulitis, impetigo, infected wounds, abscesses.
- Intra-abdominal Infections: Peritonitis, intra-abdominal abscesses.
- Gynecological Infections: Pelvic inflammatory disease (PID).

• Bone and Joint Infections: Osteomyelitis, septic arthritis.

Dosage and Administration:

- Adults and Children ≥12 years: The usual dose is 1.6g (containing 1.5g of amoxicillin and 0.3g of clavulanic acid) every 8 hours. In severe infections, the dose may be increased as directed by the healthcare provider.
- Children (3 months to 12 years): The usual dose for children is 25mg/kg to 45mg/kg of amoxicillin per day, divided into two or three doses. Neonates (under 3 months): Dosing should be determined by a healthcare provider, as it varies based on the age and severity of the infection.

Preparation and Administration:

- Reconstitute the injection with the recommended diluent (usually sterile water or normal saline) as specified in the product instructions.
- Once reconstituted, administer the solution via intravenous (IV) or intramuscular (IM) injection, as per the healthcare provider's recommendation.
- For IV administration, inject slowly over 3-4 minutes. The healthcare provider will determine the exact method and duration of administration.

Contraindications:

• History of Jaundice or Hepatic Dysfunction: Related to previous use of amoxicillin/clavulanic acid.

Precautions:

- Hypersensitivity Reactions: Use with caution in patients with a history of penicillin allergy. Severe allergic reactions (anaphylaxis) may occur.
- Renal and Hepatic Impairment: Regular monitoring is recommended for patients with renal or hepatic disease. Dose adjustments may be necessary.
- Superinfection: Prolonged use may result in overgrowth of non-susceptible organisms, including fungi.

Side Effects:

Common side effects include:

- Gastrointestinal: Nausea, vomiting, diarrhea, abdominal discomfort.
- Dermatologic: Rash, itching, or hives.
- · Headache: Mild headache may occur.

Serious side effects (rare but possible):

- Severe Allergic Reactions: Anaphylaxis, angioedema (swelling of the face, lips, tongue, or throat).
- Liver Toxicity: Hepatitis, elevated liver enzymes, jaundice.
- Severe Diarrhea: Clostridium difficileassociated diarrhea, requiring discontinuation of the drug.

Drug Interactions:

- Oral Contraceptives: Amoxicillin may reduce the effectiveness of oral contraceptives. Consider additional methods of contraception.
- Probenecid: May reduce the renal clearance of amoxicillin, leading to increased plasma concentrations.
- Methotrexate: Amoxicillin can decrease methotrexate clearance, increasing the risk of toxicity.
- Anticoagulants: Increased risk of bleeding when taken with anticoagulants such as warfarin.

- Store the injection vials at room temperature (15°C to 30°C) in a dry place, protected from light.
- After reconstitution, use the injection within 24 hours at room temperature or 48 hours if refrigerated.

Overdose:

In the case of overdose, symptoms may include gastrointestinal disturbances such as nausea, vomiting, and diarrhea. In severe cases, seizures or renal dysfunction may occur.

- Treatment is supportive and symptomatic.
- Gastric lavage or activated charcoal may be used for recent overdoses. Dialysis may assist in clearing amoxicillin and clavulanic acid from the bloodstream.

Packaging:

Amoxicillin (500mg) + Clavulanic Acid (100mg) injection is available in vials containing powder for reconstitution.

Note:

- Complete the full course of therapy as prescribed to prevent antibiotic resistance.
- Always consult a healthcare provider before starting or discontinuing the medication.
- Regular monitoring is essential for patients with renal, hepatic, or hypersensitivity issues during treatment.

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

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Storage: