

Information For the Use
Amoxicillin (250mg) + Clavulanic Acid (50mg)

Moxyplit CV 300 Injection

Amoxicillin (250mg) + Clavulanic Acid (50mg) Injection

Composition:

Each vial contains:

- **Amoxicillin (as Amoxicillin Trihydrate) - 250mg**
- **Clavulanic Acid (as Potassium Clavulanate) - 50mg**

Description:

Amoxicillin is a broad-spectrum penicillin-class antibiotic that works by inhibiting bacterial cell wall synthesis, leading to bacterial death. **Indications:**

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

- **Respiratory Tract Infections:** Pneumonia, acute otitis media, bronchitis, and sinusitis.
- **Urinary Tract Infections:** Cystitis, pyelonephritis, and other urinary infections.
- **Skin and Soft Tissue Infections:** Cellulitis, impetigo, and infected wounds.

Dosage and Administration:

- **Adults and Children ≥ 12 years:** The usual dose is 250mg of amoxicillin and 50mg of clavulanic acid every 6 to 8 hours (3-4 times a day), depending on the severity of the infection. In severe infections, the dose may be increased, as recommended by the physician.
- **Children (3 months to 12 years):** The dose for children is based on body

weight, generally 20mg to 40mg of amoxicillin per kilogram of body weight per day, divided into two or three doses, as appropriate for the infection. Dosage should be calculated by a healthcare professional.

- **Neonates (up to 3 months):** The recommended dose is lower and should be determined by the healthcare provider, as it varies based on the 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.**
- **The reconstituted solution should be administered intravenously (IV) or intramuscularly (IM), as directed by the physician. IV administration should be done slowly, and the injection should be administered over a period of at least 3-4 minutes.**

Precautions:

- **Hypersensitivity Reactions:** Use with caution in patients with a history of allergic reactions to penicillins or other beta-lactam antibiotics.
- **Renal and Hepatic Impairment:** Dose adjustments may be required in patients with renal or hepatic dysfunction.
- **Superinfection:** Prolonged use may result in the overgrowth of non-susceptible organisms, including fungi.

Side Effects:

Common side effects include:

- **Gastrointestinal:** Nausea, vomiting, diarrhea, abdominal pain.
- **Dermatologic:** Rash, itching, or skin reactions.
- **Hematologic:** Reversible changes in blood counts such as leukopenia, thrombocytopenia, or eosinophilia.
- **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, jaundice, elevated liver enzymes.
- **Severe Diarrhea:** Clostridium difficile-associated diarrhea, which may require discontinuation of the drug and appropriate treatment.

Drug Interactions:

- **Oral Contraceptives:** Amoxicillin may reduce the effectiveness of oral contraceptives. Additional contraceptive methods should be considered.
- **Probenecid:** May reduce the renal clearance of amoxicillin, leading to increased plasma concentrations.
- **Methotrexate:** Amoxicillin can reduce the clearance of methotrexate, potentially increasing its toxicity.
- **Anticoagulants:** Use with caution in combination with anticoagulants (e.g., warfarin), as amoxicillin can enhance the anticoagulant effect, increasing the risk of bleeding.

Storage:

- **Store the injection vials at room temperature (15°C to 30°C) until reconstitution.**
- **After reconstitution, the solution should be used within a specified time frame (usually 24 hours) and stored under recommended conditions (refrigerated if necessary).**
- **Do not freeze.**

Overdose:

In the event of overdose, symptoms may include gastrointestinal distress such as nausea, vomiting, and diarrhea. In severe cases, renal dysfunction or seizures may occur. Treatment is supportive and symptomatic. Gastric lavage or activated charcoal may be considered for recent overdose, and dialysis may assist in removing amoxicillin and clavulanic acid from the bloodstream.

Packaging:

Amoxicillin (250mg) + Clavulanic Acid (50mg) injection is available in vials containing the required amount of powder for reconstitution.

Note:

- **Always complete the full course of therapy as prescribed to prevent antibiotic resistance.**
- **Consult a healthcare provider before starting or discontinuing the medication.**
- **Monitor for signs of side effects or allergic reactions during treatment.**

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