# Information For the Use Amoxycillin (1000mg) + Clavulanic Acid (200mg)

# **Moxyplit CV 1.2 Injection**

Amoxicillin (1000mg) + Clavulanic Acid (200mg) Injection

# **Composition:**

# **Each vial contains:**

- Amoxicillin (as Amoxicillin Trihydrate) 1000mg
- Clavulanic Acid (as Potassium Clavulanate) - 200mg

### **Description:**

Amoxicillin is a broad-spectrum antibiotic belonging to the penicillin class of beta-lactam antibiotics. It works by inhibiting the bacterial cell wall synthesis, leading to cell death. Clavulanic acid is a beta-lactamase inhibitor that prevents bacterial enzymes (beta-lactamases) from degrading amoxicillin, thus broadening its spectrum of activity against beta-lactamase-producing bacteria.

#### **Indications:**

This combination is indicated for the treatment of infections caused by susceptible organisms, including:

- Respiratory Tract Infections: Pneumonia, acute exacerbations of chronic obstructive pulmonary disease (COPD), bronchitis, and sinusitis.
- Urinary Tract Infections: Cystitis, pyelonephritis, and other complicated urinary tract infections.
- Skin and Soft Tissue Infections: Abscesses, cellulitis, and infected wounds.
- Intra-abdominal Infections: Including peritonitis and intra-abdominal abscesses.
- Gynecological Infections: Such as pelvic inflammatory disease.
- Bone and Joint Infections: Including osteomyelitis and septic arthritis.

# **Dosage and Administration:**

- Adults and Children ≥12 years: The usual dose is 1000mg of amoxicillin and 200mg of clavulanic acid every 8 hours (three times a day), administered via slow intravenous infusion.
- Children (3 months to 12 years): The dose is determined based on body weight and the severity of the infection, as directed by the physician.
  - Infants and Children ≥3 months:
    The dose typically ranges from 20mg/kg to 40mg/kg every 8 hours.
- Renal Impairment: Dose adjustment is necessary for patients with renal impairment. The healthcare provider will adjust the dose based on the patient's creatinine clearance.
- Administration Method: Administer the injection via slow intravenous infusion over 30-60 minutes. Reconstitute the powder with the appropriate diluent before use.

#### **Contraindications:**

- Known hypersensitivity to amoxicillin, clavulanic acid, other penicillins, or any of the excipients in the formulation.
- History of jaundice or hepatic dysfunction associated with the use of amoxicillin/clavulanic acid.

#### **Precautions:**

- Hypersensitivity Reactions: Caution should be exercised in patients with a history of penicillin allergy or other hypersensitivity reactions.
- Renal and Hepatic Impairment: Adjust the dose for patients with renal or hepatic impairment.
- Superinfection: Prolonged use may result in the overgrowth of non-susceptible

- organisms, including fungi. Monitor for signs of superinfection.
- Severe Diarrhea: May be a sign of Clostridium difficile-associated diarrhea, which requires discontinuation of the drug and appropriate management.

#### **Side Effects:**

# Common side effects may include:

- Gastrointestinal: Nausea, vomiting, diarrhea, and abdominal discomfort.
- Skin: Rash or urticaria.
- Hematologic: Reversible changes in blood counts, such as thrombocytopenia or leukopenia.
- Injection Site Reactions: Pain, swelling, or redness at the injection site.

# Serious side effects (less common but possible):

- Allergic Reactions: Anaphylaxis, angioedema.
- Liver Toxicity: Hepatic dysfunction, jaundice, or elevated liver enzymes.
- Hematologic: Agranulocytosis, thrombocytopenia, hemolytic anemia.
- Clostridium difficile-associated Diarrhea: May occur in severe cases, requiring discontinuation of the antibiotic and appropriate therapy.

# **Drug Interactions:**

- Oral Contraceptives: Amoxicillin may reduce the effectiveness of oral contraceptives, and additional contraceptive methods should be considered.
- Probenecid: May decrease renal clearance of amoxicillin, leading to increased plasma levels.
- Anticoagulants (e.g., warfarin): May enhance the anticoagulant effect, increasing the risk of bleeding.
- Methotrexate: Amoxicillin may decrease methotrexate clearance, potentially increasing its toxicity.

- Store the vial in a cool, dry place at room temperature (15°C to 30°C), away from light and moisture.
- Once reconstituted, the solution should be used within 24 hours if stored at 2°C to 8°C.
- Do not freeze.

#### Overdose:

In the event of an overdose, symptoms may include gastrointestinal distress (nausea, vomiting, diarrhea), and in severe cases, renal dysfunction or seizures may occur. Supportive treatment should be initiated, and hemodialysis may help remove the drug from the system.

#### **Packaging:**

Amoxicillin (1000mg) + Clavulanic Acid (200mg) Injection is available in single-dose vials.

#### Note:

This product should be administered only by a healthcare professional. Follow the prescribed dosage and administration guidelines to ensure effectiveness and reduce the risk of adverse effects. Always complete the full course of therapy, even if symptoms improve before finishing the medication.

Manufactured in India for:



(An ISO 9001: 2015 Certified Co.)

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# Storage: