

Clariterm Injection

Clarithromycin (500mg) Injection

Composition

Each vial contains:

- Clarithromycin – 500 mg

Excipients:

- Sodium chloride, water for injection, and other suitable excipients.
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Description

Clarithromycin is a macrolide antibiotic that inhibits bacterial protein synthesis by binding to the bacterial ribosome. It is effective against a wide range of Gram-positive and Gram-negative bacteria. The injection form is indicated for use in severe infections that require intravenous (IV) therapy.

Indications

Clarithromycin 500 mg injection is used for the treatment of the following bacterial infections:

- Severe respiratory tract infections such as:
 - Pneumonia (community-acquired or hospital-acquired)
 - Acute exacerbations of chronic bronchitis
 - Sinusitis
 - Pharyngitis and tonsillitis
- Skin and soft tissue infections:
 - Abscesses, cellulitis, infected wounds
- Mycobacterium avium complex (MAC) infections in HIV/AIDS patients
- Helicobacter pylori eradication (when used in combination with other drugs for the treatment of peptic ulcer disease)

- Other serious bacterial infections as determined by the healthcare provider.
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Dosage and Administration

- Adults:
 - The usual dose is 500 mg every 12 hours by intravenous infusion for 7 to 14 days, depending on the severity of the infection.
 - For severe infections, the dose may be increased to 1 g every 12 hours, particularly in cases of pneumonia or severe skin infections.
 - For Helicobacter pylori eradication, the dose is typically 500 mg every 12 hours, in combination with other appropriate drugs.
 - Pediatric patients:
 - For children, the dose is generally 15 mg/kg/day, divided into two doses every 12 hours. It should not exceed the adult dose of 1 g per day.
 - Renal Impairment:
 - For patients with moderate to severe renal impairment, dose adjustments may be necessary.
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Mechanism of Action

Clarithromycin works by binding to the 50S subunit of the bacterial ribosome, inhibiting protein synthesis, and thereby preventing bacterial growth. Depending on the concentration, clarithromycin can act as bacteriostatic (inhibiting bacterial growth) or bactericidal (killing bacteria).

Contraindications

Clarithromycin 500 mg injection is contraindicated in the following:

- Hypersensitivity to clarithromycin or other macrolide antibiotics (e.g., erythromycin, azithromycin)
- Severe hepatic impairment
- Concomitant use with certain drugs, such as terfenadine, astemizole, cisapride, pimozide, or ergotamine, due to the risk of serious cardiovascular events.
- Pregnancy: Should only be used during pregnancy if clearly needed and prescribed by a healthcare provider.
- Breastfeeding: Clarithromycin passes into breast milk and should be used with caution during breastfeeding.

Warnings and Precautions

- **QT Interval Prolongation:** Clarithromycin can prolong the QT interval, leading to a risk of arrhythmias. It should be used with caution in patients with cardiac conditions or those on medications that also prolong the QT interval.
- **Hepatic Impairment:** Clarithromycin is metabolized in the liver, so it should be used with caution in patients with liver disease. Monitor liver function regularly.
- **Renal Impairment:** Dosage adjustments may be required for patients with kidney disease.
- **Superinfection:** Prolonged use of antibiotics can lead to the development of superinfections, including Clostridium difficile-associated diarrhea.
- **Allergic Reactions:** Severe allergic reactions, including anaphylaxis, can occur. Discontinue if any signs of hypersensitivity develop.
- **Pregnancy:** Clarithromycin is a category C drug for pregnancy. It should be prescribed only if the benefits outweigh the potential risks.

Side Effects

Common side effects may include:

- Gastrointestinal disturbances: nausea, vomiting, diarrhea, abdominal pain
- Taste disturbances: often a metallic taste
- Headache
- Rash

Serious but rare side effects include:

- Severe allergic reactions: anaphylaxis, difficulty breathing, or swelling of the face, tongue, or throat.
- Liver toxicity: jaundice, dark urine, severe abdominal pain.
- Prolonged QT interval: leading to arrhythmias (palpitations, dizziness).
- Severe diarrhea (with or without blood) due to Clostridium difficile infection.

Drug Interactions

- **Warfarin:** Clarithromycin can increase the effects of warfarin, leading to an increased risk of bleeding. Monitor INR levels closely.
- **Statins:** Clarithromycin can elevate statin levels in the blood, increasing the risk of muscle damage.
- **Rifampin:** Concurrent use can reduce the effectiveness of clarithromycin.
- **Ergotamine and Dihydroergotamine:** The use of these ergot alkaloids should be avoided due to the increased risk of ergot toxicity.

Storage

- Store in a cool, dry place between 15°C to 25°C.
- Keep the vial in the outer carton to protect it from light.
- Once diluted, the solution should be used immediately or within 24 hours when stored under refrigeration.

Note: Always follow the prescribed dosage and consult a healthcare professional if you experience any unusual symptoms or side effects.

Manufactured in India for:

CafeliTM
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Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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