

Claritem 125 Dry Syrup

Clarithromycin (125 mg) Dry Syrup

Composition

Each 5 ml of reconstituted syrup contains:

- Clarithromycin – 125 mg
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Description

Clarithromycin is a macrolide antibiotic used to treat a variety of bacterial infections. It works by inhibiting bacterial protein synthesis, thus preventing the growth of bacteria. It is effective against both Gram-positive and Gram-negative bacteria and is commonly used to treat respiratory tract infections, skin infections, and other bacterial infections.

Indications

Clarithromycin 125 mg dry syrup is indicated for the treatment of infections caused by susceptible microorganisms, including:

- Upper respiratory tract infections (e.g., pharyngitis, tonsillitis, sinusitis)
 - Lower respiratory tract infections (e.g., bronchitis, pneumonia)
 - Skin and soft tissue infections
 - Otitis media (middle ear infection)
 - Acute sinusitis
 - Infections caused by *Mycobacterium avium* complex (MAC) in patients with HIV
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Dosage and Administration

- **Adults:**

- The usual dose for respiratory tract infections is 250 mg to 500 mg twice daily.
- For skin and soft tissue infections, the recommended dose is 250 mg twice daily for 7 to 14 days.
- For *H. pylori* eradication in combination therapy: A common regimen is 250 mg to 500 mg twice daily for 14 days.

- **Pediatric patients:**

- For children over 6 months: The usual dose is 7.5 mg/kg body weight twice daily for most infections. The total dose should not exceed 500 mg per day.
- For children under 6 months, Clarithromycin should only be used if prescribed by a healthcare provider.

- **Renal impairment:** In patients with severe renal impairment, dose adjustments may be necessary.

Administration:

- The syrup should be reconstituted with water as per the instructions on the packaging.
 - Shake the bottle well before use.
 - Use a proper measuring device to ensure accurate dosing.
 - Take with or without food.
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Mechanism of Action

Clarithromycin works by inhibiting bacterial protein synthesis through binding to the 50S subunit of the bacterial ribosome. This prevents the growth and multiplication of bacteria.

Contraindications

Clarithromycin should not be used in the following situations:

- Hypersensitivity to clarithromycin, other macrolide antibiotics (e.g., erythromycin, azithromycin), or any of the ingredients in the formulation.
- Liver dysfunction (especially cholestatic jaundice or hepatic impairment).
- Concomitant use with certain drugs (e.g., terfenadine, astemizole, cisapride, pimozide, or ergotamine) due to the risk of serious cardiovascular events.

Warnings and Precautions

- **QT prolongation:** Clarithromycin can cause a prolonged QT interval, which may increase the risk of arrhythmias. Caution is required in patients with heart disease or those on medications known to prolong the QT interval.
- **Hepatic dysfunction:** Monitor liver function regularly in patients with a history of liver disease.
- **Renal impairment:** Dose adjustments may be necessary in patients with impaired renal function.
- **Pregnancy and lactation:** Clarithromycin should be used in pregnancy only when absolutely necessary and with medical advice. It is excreted in breast milk and should be used with caution during breastfeeding.

Side Effects

Common side effects may include:

- Gastrointestinal disturbances (nausea, vomiting, diarrhea, abdominal pain)
- Taste disturbance or metallic taste
- Headache
- Rash
- Liver enzyme elevation (may indicate liver damage)

- Dizziness or lightheadedness

Serious side effects (rare but severe) include:

- Severe allergic reactions (anaphylaxis, angioedema)
- Liver toxicity (yellowing of skin or eyes, dark urine)
- QT interval prolongation (potentially leading to arrhythmia)
- Clostridium difficile-associated diarrhea (can occur with prolonged use)

If any of the above serious side effects occur, seek medical attention immediately.

Storage

- Store at room temperature, between 15°C and 25°C.
- Keep the container tightly closed.
- Do not refrigerate the reconstituted syrup, but use it within the recommended period (usually 14 days after reconstitution).
- Keep out of reach of children.

Note: Always follow your healthcare provider's instructions for dosage and duration of therapy. If you experience any side effects or if the condition does not improve, consult your doctor immediately.

Manufactured in India for:

CafoliTM
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Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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