

Information For the User
Azithromycin (100mg)

Azoxone 100 Tablet

Azithromycin (100 mg) Tablet: Product Information

Brand Name: Azithromycin Tablet

Generic Name: Azithromycin

Strength: 100 mg per tablet

Dosage Form: Oral Tablet

Indications:

Azithromycin 100 mg Tablets are used for the treatment of:

- **Respiratory Tract Infections:** Such as **acute bacterial sinusitis, pharyngitis, tonsillitis, and community-acquired pneumonia.**
 - **Skin and Soft Tissue Infections:** Including infections caused by susceptible bacteria.
 - **Ear Infections:** Such as **acute otitis media.**
 - **Sexually Transmitted Infections (STIs):** Including **chlamydia, gonorrhea, and non-gonococcal urethritis.**
 - **Mycobacterium avium Complex (MAC):** Prophylaxis and treatment in immunocompromised individuals, particularly in HIV patients.
-

Mechanism of Action:

Azithromycin is a **macrolide antibiotic** that works by:

- Inhibiting **bacterial protein synthesis** by binding to the **50S ribosomal subunit** of the bacteria.
- This prevents the bacteria from producing proteins essential for their growth and survival, ultimately leading to bacterial cell death.

Azithromycin is **broad-spectrum** and effective against a wide variety of Gram-positive and Gram-negative bacteria, as well as certain atypical pathogens.

Dosage and Administration:

1. Adults and Children (depending on the infection):

- For most respiratory and skin infections, the typical dose is **500 mg on Day 1**, followed by **250 mg daily for the next 4 days.**
- For certain STIs (like chlamydia), a single dose of **1 gram** may be prescribed.
- Dosing varies by age, infection type, and severity, so follow the healthcare provider's recommendations.

2. Administration Instructions:

- Take the tablet **with or without food.**
 - Swallow the tablet whole with a full glass of water.
 - For optimal absorption, take **1 hour before or 2 hours after meals** if gastrointestinal side effects occur.
-

Contraindications:

Azithromycin 100 mg Tablet is contraindicated in:

- Patients with known **hypersensitivity** to azithromycin or other macrolide antibiotics (e.g., erythromycin, clarithromycin).
 - Individuals with a **history of liver disease** or **severe renal impairment** should use with caution.
 - Patients with a **history of QT prolongation** or **arrhythmias** should avoid azithromycin due to the potential for heart-related side effects.
-

Warnings and Precautions:

- **QT Prolongation:** Azithromycin may prolong the QT interval, which can increase the risk of serious arrhythmias, including **torsades de pointes.** Use cautiously in patients with **cardiac conditions** or who are taking **QT-prolonging drugs.**
- **Liver Disease:** Monitor liver function in patients with existing liver conditions. Discontinue if jaundice or significant liver dysfunction occurs.

- **Clostridium difficile Infection:** Antibiotics, including azithromycin, may cause an overgrowth of **Clostridium difficile**, leading to severe diarrhea. Contact a healthcare provider if diarrhea becomes severe or persists.
- **Superinfection:** Prolonged use of azithromycin may lead to overgrowth of non-susceptible organisms, including fungi and bacteria.

Side Effects:

Common side effects may include:

- **Gastrointestinal issues:** Nausea, vomiting, diarrhea, abdominal pain, or loss of appetite.
- **Headache, dizziness, or fatigue.**
- **Rash or mild allergic reactions** such as itching.

Serious but rare side effects include:

- **Severe allergic reactions:** Symptoms may include difficulty breathing, facial swelling, severe rash, or itching. Seek immediate medical attention if these occur.
- **Cardiac symptoms:** Chest pain, palpitations, or fainting due to QT prolongation. Immediate medical attention is necessary.
- **Liver issues:** Jaundice, dark urine, or abdominal pain may indicate liver problems.

If any serious side effects occur, stop using the medication and seek medical help immediately.

Drug Interactions:

- **Antacids:** Antacids containing **aluminum** or **magnesium** may interfere with the absorption of azithromycin. It is advised to take azithromycin at least **1 hour before or 2 hours after** taking antacids.
- **CYP3A4 Inhibitors:** Azithromycin may interact with drugs that inhibit the **CYP3A4 enzyme**, such as **antifungals** (e.g., ketoconazole), certain **antivirals**, and **calcium channel blockers**.
- **Warfarin:** Azithromycin may increase the anticoagulant effects of **warfarin**, increasing the risk of bleeding. Regular monitoring of **INR** (International Normalized Ratio) may be needed.
- **Ergotamine:** Concomitant use of azithromycin with **ergotamine** (used for migraine treatment)

can increase the risk of ergot toxicity, leading to serious side effects.

Storage:

- Store the **Azithromycin tablets** at **room temperature** (15°C to 30°C / 59°F to 86°F), away from moisture and heat.
- Keep the tablets in their original container, tightly closed, and out of reach of children.

Patient Counseling Information:

- **Complete the full course:** Even if symptoms improve, it's important to finish the prescribed regimen to ensure the infection is fully cleared and prevent resistance.
- **Take with or without food:** You can take the tablet with or without meals. However, for some individuals, it may be better to take it on an empty stomach.
- **Watch for side effects:** If you notice any unusual symptoms, particularly related to your heart (palpitations, dizziness) or severe gastrointestinal issues (diarrhea, stomach pain), contact your healthcare provider immediately.
- **Avoid missed doses:** If you miss a dose, take it as soon as you remember, unless it is almost time for the next dose. Do not double doses.

This product overview provides general information about **Azithromycin 100 mg Tablets**. Always follow the instructions of your healthcare provider, and consult them for specific guidance regarding dosage and treatment duration.

Manufactured in India for:

CafoliTM
L I F E C A R E

Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

Plot no.: 367-FF, Industrial Area Phase-I,
Panchkula-134113

TM: Trademark Applied for