

Information For the User
Azithromycin (500mg)

Azoxone 500 Tablet

Azithromycin (500 mg) Tablet: Product Information

Brand Name: Azithromycin 500 mg Tablet

Generic Name: Azithromycin

Strength: 500 mg per tablet

Dosage Form: Oral Tablet

Indications:

Azithromycin 500 mg tablet is an antibiotic used for the treatment of various bacterial infections caused by susceptible microorganisms. It is indicated for:

- **Respiratory Tract Infections:**
 - **Community-acquired pneumonia (CAP)**
 - **Acute bacterial sinusitis**
 - **Acute pharyngitis** (sore throat)
 - **Tonsillitis**
 - **Bronchitis**
- **Skin and Soft Tissue Infections:**
 - **Cellulitis**
 - **Erysipelas**
 - **Abscesses** or other soft tissue infections caused by susceptible bacteria.
- **Sexually Transmitted Infections (STIs):**
 - **Chlamydia infections**
 - **Non-gonococcal urethritis**
 - **Cervicitis**
- **Ear Infections:**
 - **Otitis media** (middle ear infection)
- **Pelvic Inflammatory Disease (PID):** In combination with other antibiotics, for the treatment of **PID** caused by susceptible organisms.

Mechanism of Action:

Azithromycin is a **macrolide antibiotic** that works by inhibiting bacterial protein synthesis. It binds to the **50S ribosomal subunit** of susceptible bacteria, preventing them from producing proteins necessary for their growth and replication. Azithromycin is effective against a broad spectrum of bacteria, including **Gram-positive**, **Gram-negative**, and **atypical organisms** (e.g.,

Mycoplasma pneumoniae, *Chlamydia trachomatis*, *Legionella*).

Dosage and Administration:

Adults:

- **Common Infections:**
 - For **respiratory infections** such as **community-acquired pneumonia: 500 mg once daily for 3-5 days** (or as directed by your healthcare provider).
 - For **skin and soft tissue infections: 500 mg once daily for 5-7 days**.
 - For **sexually transmitted infections (chlamydia):** A single dose of **1 gram (1000 mg)** or **500 mg once daily for 3 days**.
- **Pelvic Inflammatory Disease (PID): 500 mg once daily**, typically for 14 days, in combination with other antibiotics.

Contraindications:

Azithromycin 500 mg tablet is contraindicated in:

- **Severe hepatic impairment:** Use with caution in patients with liver disease.
- **History of cholestatic jaundice** or **liver dysfunction** caused by previous macrolide use.
- **Patients with known QT prolongation** or those using medications that may prolong the QT interval.

Warnings and Precautions:

- **QT Prolongation:** Azithromycin may cause a **prolonged QT interval**, increasing the risk of **arrhythmias**, including **torsades de pointes**. It should be used with caution in patients with existing **cardiac conditions**, electrolyte imbalances (e.g., **low potassium** or **magnesium**), and in those taking **QT-prolonging drugs**.

- **Liver Function:** Use cautiously in patients with pre-existing **liver disease**. Monitor liver function during treatment, especially in long-term therapy.
- **Allergic Reactions:** Rarely, azithromycin can cause **serious allergic reactions** like anaphylaxis or Stevens-Johnson Syndrome. Seek immediate medical help if any symptoms of a severe allergic reaction (e.g., rash, swelling, trouble breathing) occur.

Side Effects:

Common side effects include:

- **Gastrointestinal disturbances:** Nausea, vomiting, diarrhea, abdominal pain, or loss of appetite.
- **Headache or dizziness.**
- **Fatigue** or general malaise.

Serious but rare side effects include:

- **Severe allergic reactions:** Rash, swelling, difficulty breathing (anaphylaxis).
- **Cardiac issues:** Irregular heartbeats, chest pain, palpitations.
- **Liver problems:** Jaundice (yellowing of the skin or eyes), dark urine, severe upper abdominal pain.
- **Severe diarrhea or colitis:** If diarrhea is severe or persists, consult your healthcare provider immediately.

Drug Interactions:

- **CYP3A4 Inhibitors:** Azithromycin may interact with other drugs that inhibit the **CYP3A4 enzyme**, such as **antifungals** (e.g., ketoconazole), **antivirals**, **calcium channel blockers**, and **antidepressants**. These drugs may increase the level of azithromycin in the blood.
- **Antacids:** **Antacids containing magnesium or aluminum** can decrease the absorption of azithromycin. To avoid this interaction, take azithromycin at least **1 hour before** or **2 hours after** taking an antacid.
- **Warfarin:** Azithromycin may enhance the effect of **warfarin** (blood thinners), leading to a higher risk of bleeding. Monitor **INR** levels and adjust the dose of warfarin if necessary.

Storage:

- Store at **room temperature** (15°C to 30°C / 59°F to 86°F) in a dry place, away from direct light and moisture.
- Keep out of reach of children.

Patient Counseling Information:

- **Take the full course:** Even if you feel better after a few days, complete the full prescribed course of azithromycin to prevent the development of antibiotic resistance.
- **Monitor for side effects:** If you experience any **severe side effects** such as allergic reactions, chest pain, or persistent diarrhea, discontinue the medication and seek medical attention immediately.
- **Missed dose:** If you miss a dose, take it as soon as you remember unless it is close to your next dose. Do not take two doses at the same time to make up for a missed one.

This product overview provides general information on **Azithromycin 500 mg tablet**. Always follow your healthcare provider's advice on the dosage, treatment plan, and potential interactions for safe and effective use.

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