

Information For the User
Azithromycin (200mg)

Azoxone 200 Suspension

Azithromycin (200 mg/5 ml) Suspension: Product Information

Brand Name: Azithromycin Suspension

Generic Name: Azithromycin

Strength: 200 mg per 5 ml after reconstitution

Dosage Form: Oral Suspension

Indications:

Azithromycin 200 mg/5 ml Suspension is indicated 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.
- **Sexually Transmitted Infections (STIs):** Including **chlamydia, gonorrhea, and non-gonococcal urethritis.**
- **Mycobacterium avium Complex (MAC):** Prophylaxis and treatment in immunocompromised patients (particularly those with HIV).

Mechanism of Action:

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

- Inhibiting **bacterial protein synthesis** by binding to the **50S ribosomal subunit.**
- This disrupts the bacteria's ability to produce proteins essential for growth, leading to their eventual death.

Azithromycin is **broad-spectrum**, effective against a wide range of **Gram-positive and Gram-negative bacteria**, as well as **atypical pathogens** such as **Chlamydia, Mycoplasma, and Legionella.**

Dosage and Administration:

1. Reconstitution:

- If the suspension is in a dry powder form, add the specified amount of clean, boiled, and cooled water to the bottle according to the instructions provided. Shake well to ensure a uniform suspension.

2. Dosing for Adults and Children:

- **For Children (2 years and older):** The typical dose is **10 mg/kg on Day 1** (loading dose), followed by **5 mg/kg daily for the next 4 days.**
- **For Adults:** Commonly, **500 mg on Day 1**, followed by **250 mg daily for the next 4 days** (for respiratory or skin infections).

3. Administration Instructions:

- Shake the bottle well before each dose to ensure even distribution of the medication.
- Take the medication with or without food, as instructed by the healthcare provider.
- Use the provided measuring spoon, cup, or syringe to ensure the correct dosage.

Contraindications:

Azithromycin 200 mg/5 ml Suspension is contraindicated in:

- Individuals with known **hypersensitivity** (allergy) to azithromycin, other macrolide antibiotics (e.g., erythromycin, clarithromycin), or any component of the formulation.
- Patients with a history of **liver disease** or severe **renal impairment** should use the medication with caution.

Warnings and Precautions:

- **QT Interval Prolongation:** Azithromycin can cause QT prolongation, which may increase the risk of **torsades de pointes** (a life-threatening arrhythmia). Use cautiously in patients with known **cardiac conditions, electrolyte**

imbalances, or those taking other drugs that affect the heart rhythm.

- **Liver Disease:** Use with caution in patients with liver disease, and monitor for signs of **liver dysfunction**, such as jaundice, dark urine, or persistent abdominal pain.
- **Clostridium difficile-associated Diarrhea (CDAD):** Antibiotics like azithromycin may lead to an overgrowth of **C. difficile**, causing severe diarrhea. Seek medical attention if diarrhea becomes severe or persists after treatment.
- **Superinfection:** Prolonged use of azithromycin may lead to the overgrowth of non-susceptible organisms, including fungi. Discontinue treatment if a superinfection develops.

Side Effects:

Common side effects may include:

- **Gastrointestinal symptoms:** 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:** Such as difficulty breathing, facial swelling, or severe rash. Seek immediate medical help if these occur.
- **Heart-related issues:** Chest pain, palpitations, or fainting. Seek urgent medical attention if these symptoms develop.
- **Liver problems:** Jaundice, dark urine, or pain in the upper abdomen may indicate liver dysfunction.

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

Drug Interactions:

- **Antacids:** Taking antacids containing **aluminum** or **magnesium** may reduce the absorption of azithromycin. It is advised to take azithromycin at least **1 hour before or 2 hours after** antacids.
- **CYP3A4 Inhibitors:** Azithromycin may interact with drugs that inhibit **CYP3A4**, such as **antifungals** (e.g., ketoconazole), **calcium channel blockers**, and certain **antivirals**. This may affect drug metabolism.

- **Warfarin:** Azithromycin may increase the effect of **warfarin** (a blood thinner), increasing the risk of bleeding. Regular monitoring of the **INR** (International Normalized Ratio) is recommended.
- **Ergotamine:** Avoid combining azithromycin with **ergotamine** (used for migraine treatment) as it may increase the risk of ergot toxicity.

Storage:

- Store the **unreconstituted powder** at **room temperature** (15°C to 30°C / 59°F to 86°F), protected from heat and moisture.
- After reconstitution, store the suspension in a **refrigerator** (2°C to 8°C / 36°F to 46°F) and use within **10 days**. Do not freeze.
- Keep the medication out of the reach of children.

Patient Counseling Information:

- **Shake well before use:** Always shake the suspension thoroughly before each dose to ensure uniform distribution of the medication.
- **Complete the prescribed course:** Even if you feel better, it is important to finish the full course of antibiotics to ensure the infection is completely eradicated.
- **Use the correct measuring device:** Always use the provided spoon or syringe for accurate dosing.

This product overview provides general information on **Azithromycin 200 mg/5 ml Suspension**. Always follow the healthcare provider's instructions, and consult them for specific guidance regarding dosage and treatment duration.

Manufactured in India for:

CafoliTM
L I F E C A R E

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(An ISO 9001: 2015 Certified Co.)

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