

Information For the User
Azithromycin (100mg)

Azoxone 100 Suspension

Azithromycin (100 mg) Suspension: Product Information

Brand Name: Azithromycin Suspension

Generic Name: Azithromycin

Strength: 100 mg per 5 ml

Dosage Form: Oral Suspension

Indications:

Azithromycin 100 mg Suspension is indicated for the treatment of:

- **Respiratory infections:** Such as **acute bacterial sinusitis, pharyngitis, tonsillitis, community-acquired pneumonia, and acute exacerbations of chronic obstructive pulmonary disease (COPD).**
- **Skin and soft tissue infections:** Including infections caused by susceptible strains of bacteria.
- **Ear infections:** Such as **otitis media** (middle ear infections).
- **Other infections:** Azithromycin is also used for certain **sexually transmitted infections (STIs)**, such as **chlamydia** and **gonorrhea**, as well as **Mycobacterium avium complex (MAC)** infections in immunocompromised individuals.

Mechanism of Action:

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

- Inhibiting bacterial protein synthesis by binding to the **50S ribosomal subunit**.
- This action prevents bacteria from producing proteins necessary for their growth and replication, effectively stopping the infection.

Azithromycin has a **broad spectrum of activity**, including coverage against Gram-positive and Gram-negative bacteria, as well as some atypical pathogens.

Dosage and Administration:

1. **Reconstitution:** If the suspension is in a dry powder form, reconstitute it with the prescribed amount of water according to the package instructions.
2. **Dosing for Adults and Children:**
 - The usual pediatric dose of Azithromycin 100 mg/5 ml Suspension is **10 mg/kg on day 1** (loading dose), followed by **5 mg/kg once daily** for the next 4 days.
 - **Adults:** For conditions like respiratory infections, the typical dose is **500 mg on day 1**, followed by **250 mg daily for the next 4 days**.
3. **Administration Instructions:**
 - Shake the suspension well before each dose to ensure uniform distribution of the drug.
 - Administer the suspension with or without food as directed by the healthcare provider.
 - Use the provided measuring device (e.g., spoon, syringe) for accurate dosing.

Contraindications:

Azithromycin 100 mg Suspension is contraindicated in:

- Individuals with known **hypersensitivity** (allergy) to azithromycin, other macrolide antibiotics (e.g., erythromycin, clarithromycin), or any component of the suspension.
- Patients with a history of **liver disease** or severe **renal impairment**, as the drug is metabolized by the liver and excreted by the kidneys.

Warnings and Precautions:

- **QT Interval Prolongation:** Azithromycin can cause prolongation of the QT interval, which may increase the risk of **torsades de pointes** (a type of abnormal heart rhythm). Use cautiously in patients with a history of **arrhythmias** or **heart disease**.
- **Liver and Kidney Function:** Use with caution in patients with liver or kidney dysfunction.

Monitor liver enzymes and kidney function during prolonged therapy.

- **Clostridium difficile-associated diarrhea (CDAD):** Antibiotic use, including azithromycin, can lead to **Clostridium difficile** infection, which may cause severe diarrhea. If diarrhea occurs, contact a healthcare provider immediately.

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 or swelling.

Serious but rare side effects include:

- **Severe allergic reactions:** Such as difficulty breathing, facial swelling, or severe skin reactions. Immediate medical attention is necessary if these occur.
- **Heart-related issues:** Irregular heartbeat or palpitations, especially in those with pre-existing heart conditions.

In cases of serious side effects, discontinue the medication and seek medical help immediately.

Drug Interactions:

- **Antacids:** Taking antacids containing aluminum or magnesium may reduce the absorption of azithromycin. It's recommended 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, affecting drug metabolism. Check with a healthcare provider before using with medications like **antifungals (e.g., ketoconazole)**, **certain antivirals**, or **calcium channel blockers**.
- **Warfarin:** Caution should be used when azithromycin is taken with warfarin (a blood thinner), as it may increase the risk of bleeding.

Storage:

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

Patient Counseling Information:

- **Shake well before use:** Always shake the suspension thoroughly before each dose to ensure uniformity.
- **Complete the full course:** Even if you start feeling better, continue the full prescribed course to prevent the infection from returning.
- **Inform your healthcare provider:** If you experience any allergic reactions, heart symptoms, or gastrointestinal issues during treatment.
- **Take with food or milk:** This can help reduce gastrointestinal discomfort.

This overview provides general information on **Azithromycin 100 mg/5 ml Suspension**. Always follow the healthcare provider's instructions and consult them for specific guidance on this medication.

Manufactured in India for:

CafoliTM
L I F E C A R E

Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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