

# AZOMYCIN

## Antibacterial Agent Capsules, Suspension

### Composition:

#### Capsules

Each capsule contains:

**Active ingredient:** Azithromycin dihydrate equivalent to azithromycin 250mg

**Excipients:** Starch, magnesium stearate, sodium lauryl sulphate, lactose, and hard gelatin shell.

#### Suspension

Each 5mL (teaspoonful) of the reconstituted suspension contains:

**Active ingredient:** Azithromycin dihydrate equivalent to azithromycin 200mg

**Excipients:** Sucrose, sodium phosphate, sodium benzoate, hydroxy propyl cellulose, xanthan gum, and fruit flavors.

### Properties

Azithromycin, the active ingredient of **AZOMYCIN**, is an azalide, a subclass of macrolide antibiotics, having a broad-spectrum activity against many Gram-positive and Gram-negative aerobic and anaerobic bacteria. It acts by binding to the 50s ribosomal subunit of the 70s ribosome of susceptible organisms, thereby inhibiting RNA-dependent protein synthesis.

**AZOMYCIN** is bactericidal for *Streptococcus pyogenes*, *Streptococcus pneumoniae*, and *Haemophilus influenzae*; it is bacteriostatic for *Staphylococci* and most aerobic Gram-negative species.

Following oral administration, azithromycin is rapidly absorbed and widely distributed throughout the body. It has a bioavailability of about 37%. Volume of distribution is approximately 31 L/Kg and peak plasma concentrations are achieved within 2.1 - 3.2 hours after administration. It gets concentrated intracellularly resulting in higher tissue concentrations than those in plasma or serum. The long tissue half-life, which ranges between 2 - 4 days, is the reason of being recommended once daily. Azithromycin is highly concentrated in phagocytes and fibroblasts as well. Concentration in phagocytes may contribute to drug distribution to inflamed tissues. Protein binding varies according to concentration from 7% at 1mcg/mL to 50% at 0.02 - 0.05mcg/mL. About 50% of the oral dose is excreted through biliary excretion in the unchanged form, while only 4.5% is excreted in the urine as unchanged drug within 72 hours of its administration.

### Indications

**AZOMYCIN** is indicated in the treatment of the following infections:

- 1 - Lower Respiratory Tract Infections
  - Mild to moderate acute bacterial exacerbations of chronic bronchitis due to *Hemophilus influenzae*, *Moraxella catarrhalis*, or *Streptococcus pneumoniae*.
  - Community acquired pneumonia of mild severity due to *Hemophilus influenzae* or *Streptococcus pneumoniae*.
- 2 - Upper Respiratory Tract Infections
  - In patients who cannot tolerate first line therapy (penicillins), **AZOMYCIN** can be used as an alternative therapy in treating mild to moderate streptococcal pharyngitis/tonsillitis and sinusitis.
- 3 - Acute otitis media due to *Hemophilus influenzae*, *Streptococcus pneumoniae*, and *Moraxella catarrhalis*.
- 4 - Uncomplicated skin and soft tissue infections due to *Staphylococcus aureus*, *Streptococcus pyogenes*, or *Streptococcus agalactiae*.
- 5 - Uncomplicated urethritis and cervicitis due to *Chlamydia trachomatis*,

### Dosage

**AZOMYCIN** should be taken on an empty stomach, one hour before or two hours after a meal.

#### Adults and children more than 45 kg body weight

Usual dose: 500mg (2 capsules or 12.5mL or 2<sup>1</sup>/<sub>2</sub> teaspoonfuls) once daily for 3 days.

Uncomplicated chlamydial urethritis and cervicitis: a single dose of 1g (4 capsules or 25mL or 5 teaspoonfuls) is usually recommended.

#### Children 45 kg body weight and less

**AZOMYCIN** suspension should not be given to infants under 6 months of age until further evidence confirms its safety in this age group.

The recommended dose in children over 6 months is 10mg/kg body weight once daily for 3 days.

A common dosage regimen (for children more than 15kg/body weight) is as follows:

Children 15 - 25kg (3 - 7 years): 200mg (1 teaspoonful or 5mL) once daily for 3 days.

Children 26 - 35kg (8 - 11 years): 300mg (1<sup>1</sup>/<sub>2</sub> teaspoonful or 7.5mL) once daily for 3 days.

Children 36 - 45kg (12 - 14 years): 400mg (2 teaspoonfuls or 10mL) once daily for 3 days.

**Note:** Use the measuring spoon provided inside the box for proper measurement of the dose.

**If you miss a dose**

- Take the missed dose as soon as you remember.
- If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose.
- Do not take two doses at one time.

**Contraindications**

It should not be used in patients with history of hypersensitivity to azithromycin or any other ingredient, as well as to any other macrolide.

It is contraindicated in patients with hepatic impairment, as jaundice has been reported in some cases.

**Precautions**

Azithromycin should not be used in patients with pneumonia who are inappropriate for outpatient oral therapy because of moderate to severe illness or in patients with pneumonia who are elderly or debilitated, have nosocomial infections, have known or suspected bacteremia, or may have an impaired immune response.

As with other macrolides, caution is recommended in patients suffering from prolongation of QT interval, as ventricular tachycardia has been reported rarely.

Caution is also recommended in patients with porphyria

**Renal impairment:** As there is no information available regarding the safe use of azithromycin in patients with moderate to severe renal impairment, caution is usually advised in such cases.

**Pregnancy and lactation:** Azithromycin is not reported to be harmful during pregnancy and lactation as adequate and well-controlled studies in humans have not been done. However, it is advised to use only if suitable alternatives are not available.

**Side Effects**

Some minor side effects may be experienced by patients receiving azithromycin.

These may include gastrointestinal disturbances such as anorexia, dyspepsia, nausea, vomiting, abdominal discomfort, diarrhea (antibiotic associated colitis), and constipation.

Some allergic reactions may infrequently occur such as skin rash and urticaria.

Some CNS disorders including dizziness, headache, drowsiness, asthenia, paraesthesia, and convulsions may rarely occur.

Reversible hearing loss has been reported after ingestion of large doses, tinnitus, taste disturbances, photosensitivity, cholestatic jaundice, hepatitis, hepatic necrosis, hepatic failure, interstitial nephritis, acute renal failure, mild neutropenia, cardiac effects (including chest pain and arrhythmia), Stevens-Johnson syndrome, and toxic epidermal necrolysis have been reported rarely.

**Drug Interactions**

Aluminium- and magnesium- containing antacids may delay the absorption of azithromycin, but have no effect on the extent of absorption. Azithromycin should be administered at least 1 hour before or 2 hours after these antacids.

As with other macrolides, azithromycin may possibly increase plasma concentration of some drugs upon concomitant administration. These include cyclosporin (inhibit metabolism), bromocriptine and cabergoline, digoxin (enhanced effect), and rifabutin (due to the risk of uveitis which may require reduction of rifabutin dose).

Concurrent use of warfarin or acenocoumarol with macrolide antibiotics has been associated with enhanced anticoagulant effects; prothrombin time should be monitored carefully upon concurrent administration.

Concomitant use of reboxetine (antidepressant agent) with macrolides should be avoided.

As with other macrolides, azithromycin may possibly inhibit the metabolism of mizolastine; concomitant administration should be avoided.

Concurrent administration of ritonavir may possibly increase plasma concentration of macrolides.

**Presentations**

**AZOMYCIN** capsules: Packs of 6 capsules.

**AZOMYCIN** suspension: Bottles of 15mL and 30mL after reconstitution.

\* Store at a temperature of 15-25°C, in a dry place. After mixing the suspension, store in a refrigerator and use within 7 days.

**THIS IS A MEDICAMENT**

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers,  
Union of Arab Pharmacists.

Any information ? Call Our Toll Free No. (971) 800-4994



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