

Azithromycin USP

Composition

**Capsule 250** : Each capsule contains Azithromycin USP 250 mg.  
**Tablet 500** : Each film-coated tablet contains Azithromycin USP 500 mg.

**Powder for 15 ml Suspension** : When reconstituted, each 5 ml suspension contains Azithromycin USP 200 mg.

**Powder for 30 ml Suspension** : When reconstituted, each 5 ml suspension contains Azithromycin USP 200 mg.

**Powder for 50 ml Suspension** : When reconstituted, each 5 ml suspension contains Azithromycin USP 200 mg.

Pharmacology

**Azin®** (Azithromycin) is an azalide, a subclass of macrolide antibiotics, active against Gram-positive and Gram-negative organisms for oral administration. Following oral administration, it is rapidly absorbed and widely distributed throughout the body. Azin® (Azithromycin) acts by binding to the 50s ribosomal subunit of susceptible organisms and thus interfering with microbial protein synthesis.

Indications

**Azin®** (Azithromycin) is indicated in upper respiratory tract infections, including pharyngitis, tonsillitis, sinusitis, otitis media; lower respiratory tract infections including bronchitis, pneumonia; skin and soft tissue infections and typhoid fever. In sexually transmitted diseases in men and women Azin® (Azithromycin) is indicated in the treatment of uncomplicated genital infections due to *Chlamydia trachomatis*.

Dosage And Administration

**Route of administration** : Oral

**Adults** :

Infections	Dose
Upper respiratory tract infections, including sinusitis, pharyngitis, tonsillitis, otitis media; lower respiratory tract infections including bronchitis, pneumonia; Skin and soft tissue infections.	2 capsules/tablets of Azin® 250 mg or 1 tablet of Azin® 500 mg once daily for 3 days. An alternative to this dosage schedule is 2 capsules/tablets of Azin® 250 mg or 1 tablet of Azin® 500 mg once for first day, followed by 1 capsule/tablet of Azin® 250 mg once daily for next 4 days.
Sexually transmitted diseases caused by <i>Chlamydia trachomatis</i> .	4 capsules/tablets of Azin® 250 mg or 2 tablets of Azin® 500 mg given as a single dose.
Typhoid fever.	500 mg once daily for 7 days.

Children :

The dose of Azin® in children over 6 months of age is 10 mg/kg body weight once daily for 3 days. Alternatively, 10 mg/ kg on day 1, followed by 5 mg / kg for next 4 days is also recommended. There is no information on use of Azin® (Azithromycin) on children under 6 months of age.

For children the dose of AZIN® suspension is as follows :

Age (Body weight)	Dose
3-7 years (15-25 kg)	1 measuring spoonful (5 ml) once daily for 3 days.
8-11 years (26-35 kg)	1½ measuring spoonful (7.5 ml) once daily for 3 days.
12-14 years (36-45 kg)	2 measuring spoonful (10 ml) once daily for 3 days.
Over 14 years (Over 45 kg)	The dose is as for adults.

OR AS DIRECTED BY THE PHYSICIAN.

Contraindications

Azithromycin is contraindicated in patients with known hypersensitivity to Azithromycin and with hepatic disease.

Warning & Precaution

Azithromycin absorption is reduced by 50% in presence of food in the stomach. It should therefore be taken 1 hour before or 2 hours after meal. Macrolides have been known to increase the plasma concentration of digoxin and cyclosporin. Therefore, if coadministration is necessary caution should be exercised and serum level of digoxin and cyclosporin should be checked. Precaution should be taken in patients with hepatic and severe renal impairment.

Side Effects

**Common side effects** : Azithromycin is well tolerated with a low incidence of side effects. Majority of the side effects is mild to

moderate in nature and of gastrointestinal in origin with nausea, abdominal discomfort, vomiting, flatulence, diarrhoea and loose motion. Allergic reactions, such as rash may be occurred in case of hypersensitive patients.

**Rare side effects** : Abnormally Low Blood Pressure, Acute Kidney Failure, Bronchospasm, Hearing Loss, Hepatitis, Liver Tissue Death, Pancreatitis, Seizures, Stevens-Johnson Syndrome

Use In Pregnancy & Lactation

Pregnancy Category B. There is no adequate and well-controlled studies of Azithromycin in pregnant women. Azithromycin should be used during pregnancy only if clearly needed.

It is not known whether Azithromycin is excreted in breast milk. Because many drugs are excreted in breast milk, caution should be exercised when Azithromycin is administered to a nursing woman.

Use In Children & Adolescents

Safety and effectiveness in the treatment of patients under 6 months of age have not been established.

Drug Interactions

**With Medicine** : Azithromycin absorption is reduced in presence of antacid. So, Azithromycin should be administered 1 hour before or 2 hours after taking antacid.

**With food & others** : Azin® tablet, capsule and oral suspension can be taken with or without food.

Direction For Reconstitution of Suspension

**15 ml** : Shake the bottle to loosen the powder. Pour 8 ml (measure 4 ml two times with the provided measuring cylinder) boiled & cooled water into the bottle. For ease of preparation, add 4 ml of water and shake well. Then again add 4 ml of water and shake well until all the powder is in suspension. The reconstituted suspension should be used within 7 days at room temperature and 14 days by preserving it at refrigerator.

**30 ml** : Shake the bottle to loosen the powder. Pour 16 ml (measure 8 ml two times with the provided measuring cup) boiled & cooled water into the bottle. For ease of preparation, add 8 ml of water and shake well. Then again add 8 ml of water and shake well until all the powder is in suspension. The reconstituted suspension should be used within 7 days at room temperature and 14 days by preserving it at refrigerator.

**50 ml** : Shake the bottle to loosen the powder. Pour 30 ml (measure with the provided measuring cup 10 ml marked three times) boiled & cooled water into the bottle. For ease of preparation, add 10 ml of water and shake well. Then add 10 ml of water and shake well. Again add 10 ml of water and shake well until all the powder is in suspension. The reconstituted suspension should be used within 7 days at room temperature and 14 days by preserving it at refrigerator.

Shake the bottle before each use.

Overdose

Adverse reactions experienced at higher than recommended doses are similar to those seen at normal doses particularly nausea, diarrhea, and vomiting.

Storage

Store below 30° C and dry place protected from light. Keep all medicines out of reach of children.

Packing

**Capsule 250** : Each box contains 2x3 capsules in Alu-PVDC blister.  
**Tablet 500** : Each box contains 2x6 Tablets in Alu-Alu blister.

**Powder for 15 ml Suspension** : Each carton contains required amount of powder to prepare 15 ml suspension in glass bottle, a measuring cylinder and a dropper.

**Powder for 30 ml Suspension** : Each carton contains required amount of powder to prepare 30 ml suspension in glass bottle, a measuring cup and a dropper.

**Powder for 50 ml Suspension** : Each carton contains required amount of powder to prepare 50 ml suspension in glass bottle and a measuring cup.

★ Further information is available on request.



Manufactured by:  
**The ACME Laboratories Ltd.**  
Dhulivita, Dhamrai, Dhaka, Bangladesh  
For Health, Vigour and Happiness

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