

Composition

Azinil 250 Tablet : Each film coated tablet contains Azithromycin USP 250 mg as Azithromycin Dihydrate USP.

Azinil 500 Tablet : Each film coated tablet contains Azithromycin USP 500 mg as Azithromycin Dihydrate USP.

Azinil 20, 35 & 50 ml Powder for Suspension : After reconstitution each 5 ml suspension contains Azithromycin USP 200 mg as Azithromycin Dihydrate USP.

Pharmacology

Azinil contains Azithromycin Dihydrate USP an azalide, a subclass of macrolide antibiotics, for oral administration. Following oral administration, Azithromycin is rapidly absorbed and widely distributed throughout the body. Azithromycin acts by binding to the 50s ribosomal subunit of susceptible microorganisms and thus interfering with microbial protein synthesis. Azithromycin is active against both Gram-positive & Gram-negative microorganisms.

Indication

Azinil is indicated in lower respiratory tract infections including bronchitis & pneumonia, otitis media and in upper respiratory tract infections including sinusitis & pharyngitis/ tonsillitis, skin & soft tissue infections, mild to moderate typhoid fever due to multiple-antibacterial resistant organisms, cholera in children & adult and sexually transmitted diseases both in men & women. **Azinil** is also indicated for the treatment of uncomplicated genital infections due to *Chlamydia trachomatis* and urethritis & cervicitis due to *Chlamydia trachomatis* & *Neisseria gonorrhoea*.

Dosage & Administration

Azinil Tablet can be taken with or without food.

Azinil Suspension should be taken at least 1 hour before or 2 hours after meal.

Adults

Indications	Dose
URTIs, LRTIs, SSTIs & Dental Infections	500 mg once daily for 3-5 days Or, 500 mg as a single dose on Day 1, followed by 250 mg once daily on Days 2-5
Acute bacterial sinusitis	500 mg once daily for 3-5 days
Acne Vulgaris caused by <i>Propionibacterium acne</i> (known as pulse therapy)	500 mg once daily consecutive 3 days for 12 weeks
Uncomplicated Genital Chlamydial Infections & Uncomplicated Gonorrhoea, Non-gonococcal urethritis & cervicitis	Single 1 gm
Cholera & Diarrhea	Respectively single 1 gm & 500 mg
Uncomplicated typhoid fever	1 gm once daily for 5 days

Elderly - Normal adult dose is recommended.

Children

The recommended dose of Azinil especially for acute otitis media, acute bacterial sinusitis & community-acquired pneumonia in children over 6 months of age is 10 mg/kg body weight once daily for 3 days or 10 mg/kg on Day 1, followed by 5 mg/kg for next 4 days.

Body Weight (Age)	Volume ml (Teaspoon)	Duration of Treatment
5-10 Kg (6 months - 2 years)	1.25–2.5 ml (¼ - ½ tsp)	Once daily for 3 days
11 - 20 Kg (3 - 8 years)	5 ml (1 tsp)	Once daily for 3 days
21 - 30 Kg (9 - 12 years)	7.5 ml (1 ½ tsp)	Once daily for 3 days
31 - 40 Kg (13 - 15 years)	10 ml (2 tsp)	Once daily for 3 days
41 - 45 Kg (16 - 17 years)	11.5 ml (2 ½ tsp)	Once daily for 3 days
For body weight over 45 Kg, normal adult dose is recommended		

Typhoid fever (3-17 years): 20 mg/kg for 5 days (maximum dose 1000 mg/day) or 10 mg/kg for 7 days (maximum dose 500 mg/kg).

Contraindication

Azinil is contraindicated in patients with known hypersensitivity to Azithromycin, Erythromycin or any of the macrolide antibiotics.

Precaution

As with any antibiotic preparation, observation for signs of superinfection with non-susceptible organisms, including fungi, is recommended. Caution should be exercised when Azithromycin is administered to subjects with severe renal impairment. Azithromycin is principally eliminated via the liver, so caution should be exercised when Azithromycin is administered to patients with impaired hepatic function.

Side Effect

Azinil is well tolerated with a low incidence of side effects. Majority of the side effects are mild to moderate in nature and of gastro-intestinal in origin with nausea, abdominal discomfort, vomiting, flatulence and diarrhea. Allergic reactions such as rash have occurred and there have also been rare reports of serious hypersensitivity reactions. Reversible elevations in liver transaminase have been seen with a frequency similar to the comparative macrolides and penicillins used in clinical trials.

Use in Pregnancy & Lactation

Pregnancy: Pregnancy Category B.

Lactation: Caution should be exercised when Azithromycin is administered to a nursing mother.

Drug Interaction

Antacids - in patients receiving Azithromycin and antacid, Azithromycin should be taken at least 1 hour before or 2 hours after antacid. Cyclosporin & Digoxin - Macrolides interfere with the metabolism of cyclosporin & digoxin. Ergot derivatives - Because of the theoretical possibility of ergotism, Azithromycin and ergot derivatives should not be administered. Terfenadine - As with other macrolides, Azithromycin should be administered with caution in combination with terfenadine.

Overdose

There is no data on overdose with Azithromycin. Typical symptoms of overdose with macrolide antibiotics include hearing loss, severe nausea, vomiting and diarrhea. Gastric lavage and general supportive measures are indicated.

Preparation of suspension

To prepare **Azinil 20, 35 & 50 ml suspension**, first shake the bottle to loosen the powder, then add 15, 25 & 35 ml or 3, 5 & 7 teaspoonful (with supplied 10 ml measuring cup) boiled and cooled water respectively into the bottle and shake well to mix uniformly.

Storage

Keep away from light & moisture and store below 30° C. Keep out of the reach of children.

Packaging

Azinil 250 Tablet : Each box contains 3 x 4's Tablet in Alu-Alu blister pack.

Azinil 500 Tablet : Each box contains 3 x 4's Tablet in Alu-Alu blister pack.

Azinil 20/35/50 ml Dry Powder for Suspension : Each box containing sealed cap bottle containing dry powder for reconstituting 20/35/50 ml suspension with a 10 ml measuring cup and a dropper.