

Azinil

Azithromycin

250 mg Tablet
500 mg Tablet
200 mg/5 ml PFS

Description

Azinil (Azithromycin) is an antibiotic belongs to macrolide class. It acts by binding to the 50s ribosomal subunit of susceptible microorganisms and thus interferes with microbial protein synthesis. Azithromycin has been shown to be active against most strains of the Gram-positive and Gram-negative organisms. Azithromycin is widely distributed throughout the body. Peak plasma concentration is achieved within 2-3 hours. The elimination half-life is 64 hours.

Composition

Azinil-250 Tablet : Each tablet contains Azithromycin Dihydrate USP equivalent to Azithromycin 250 mg.

Azinil-500 Tablet : Each tablet contains Azithromycin Dihydrate USP equivalent to Azithromycin 500 mg.

Azinil-PFS (20 ml & 35 ml) : After reconstitution each 5 ml suspension contains Azithromycin Dihydrate USP equivalent to Azithromycin 200 mg.

Indication

Azinil (Azithromycin) is indicated in-

- **Acute bacterial exacerbations of chronic obstructive pulmonary disease** due to *Haemophilus influenzae*, *Moraxella catarrhalis* or *Streptococcus pneumoniae*.
- **Acute bacterial sinusitis** due to *Haemophilus influenzae*, *Moraxella catarrhalis* or *Streptococcus pneumoniae*.
- **Community-acquired pneumonia** due to *Chlamydia pneumoniae*, *Haemophilus influenzae*, *Mycoplasma pneumoniae* or *Streptococcus pneumoniae*.
- **Pharyngitis/tonsillitis** caused by *Streptococcus pyogenes*.
- **Uncomplicated skin and skin structure infections** due to *Staphylococcus aureus*, *Streptococcus pyogenes*, or *Streptococcus agalactiae*.
- **Urethritis and cervicitis** due to *Chlamydia trachomatis* or *Neisseria gonorrhoeae*.
- **Genital ulcer disease** due to *Haemophilus ducreyi* (chancroid).

Dosage and Administration

Azinil tablet (Azithromycin) can be taken with or without food.

Azinil-PFS (Azithromycin) should be taken at least 1 hour before or 2 hours after meal.

Adults dosage schedule

Infection	Dose/Treatment duration
Community-acquired pneumonia Pharyngitis/tonsillitis Skin and skin structure	500 mg as a single dose on Day 1, followed by 250 mg once daily on Days 2 through 5
Acute bacterial exacerbations of chronic obstructive pulmonary disease	500 mg once daily for 3 days or 500 mg as a single dose on Day 1, followed by 250 mg once daily on Days 2 through 5
Acute bacterial sinusitis	500 mg once daily for 3 days
Genital ulcer disease (chancroid)	Single 1 gm dose
Non-gonococcal urethritis and cervicitis	Single 1 gm dose
Gonococcal urethritis and cervicitis	Single 2 gm dose
Typhoid fever	500 mg twice daily for 7 days

Children dosage schedule

The recommended dose of **Azinil** (Azithromycin) especially for acute otitis media, acute bacterial sinusitis and 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	Dose/Treatment duration
15-25 kg (3-7 years)	200 mg (5 ml Azinil-PFS) once daily for 3 days
26-35 kg (8-11 years)	300 mg (7.5 ml Azinil-PFS) once daily for 3 days
36-45 kg (12-14 years)	400 mg (10 ml Azinil-PFS) once daily for 3 days
Over 45 kg	Normal adults dosage is recommended

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

Hepatic impairment : Dose adjustment is not necessary. **Renal impairment** : Dose adjustment is not necessary with GFR \leq 80 ml/min but caution should be exercised in severe renal impairment (GFR < 10 ml/min)

Contraindication

Azinil is contraindicated in patients with i.) known hypersensitivity to azithromycin, erythromycin or any macrolide antibiotic ii.) Hepatic impairment iii.) Co-administration with ergot derivatives, terfenadine, astemizole.

Precaution

As with any antibiotic, observations for signs of superinfection with non-susceptible organisms, including fungi, is recommended. Precaution should be taken in patients with severe renal impairment.

In pregnancy & lactation

Pregnancy : Pregnancy Category B. Azithromycin should be used during pregnancy only if clearly needed. **Lactation** : It is not known whether Azithromycin is excreted in human milk; caution should be exercised when Azithromycin is administered to nursing mother.

Side Effect

Azithromycin is well tolerated with a low incidence of side effects. The side effects include nausea, vomiting, abdominal discomfort (pain/ cramps), flatulence, diarrhoea, headache, dizziness and skin rashes and are reversible upon discontinuation of therapy.

Drug Interaction

Nelfinavir : increased azithromycin serum concentrations. **Warfarin** : increased anticoagulant effects. **Atorvastatin**, **carbamazepine**, **cetrizine**, **didanosine**, **efavirenz**, **fluconazole**, **indinavir**, **midazolam**, **rifabutin**, **sildenafil**, **theophylline** (intravenous and oral), **triazolam**, **trimethoprim/sulfamethoxazole** or **zidovudine** : Azithromycin had a modest effect on their pharmacokinetics. **Digoxin** : elevated digoxin concentrations. **Ergotamine** or **dihydroergotamine** : Azithromycin caused acute ergot toxicity. **Terfenadine**, **cyclosporine**, **hexobarbital** and **phenytoin** : Azithromycin increases their plasma concentrations.

Direction for reconstitution of Azinil-PFS

Shake the bottle until all powder flows freely. Add 10 ml (2 teaspoonfull) boiled & cool water for **Azinil-20 ml PFS** and add 15 ml (3 teaspoonfull) boiled & cool water for **Azinil-35 ml PFS** & shake vigorously to suspend powder. For better mixing add total water in two portion and shake vigorously each time.

Note : After reconstitution keep the bottle tightly closed and shake the bottle well before each use. Reconstituted suspension must be used within 7 days if kept at room temperature or within 10 days (**Azinil-20 ml PFS**) & 14 days (**Azinil-35 ml PFS**) when stored in a refrigerator.

Storage

Store in cool dry place and away from light. Keep out of the reach of children.

How supplied

Azinil-250 Tablet : Each box containing 2 x 3's Tablet in Alu-Alu Blister strips.

Azinil-500 Tablet : Each box containing 2 x 3's Tablet in Alu-Alu Blister strips.

Azinil-20 ml PFS : Bottle containing Azithromycin powder to make 20 ml suspension when reconstituted.

Azinil-35 ml PFS : Bottle containing Azithromycin powder to make 35 ml suspension when reconstituted.



Manufactured by
Apex Pharma Ltd.
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