

Composition:

Azee Tablet: Each film coated tablet contains Azithromycin Dihydrate USP equivalent to Azithromycin 500 mg

Pharmacology:

Azee (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.

Indications:

Azee (Azithromycin) is indicated in-

- Acute bacterial exacerbations of chronic obstructive pulmonary disease due to Haemophilus influenza, Moraxella catarrhalis or Streptococcus pneumonia.
- Acute bacterial sinusitis due to Haemophilus influenza, Moraxella catarrhalis or Streptococcus pneumoniae.
- Community-acquired pneumonia due to Chlamydia pneumonia, Haemophilus influenza, Mycoplasma pneumonia or Streptococcus pneumonia.
- 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 gonorrhoea.
- Genital ulcer disease due to Haemophilus ducreyi (chancroid).

Dosage and Administration:

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

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

Hepatic impairment: Dose adjustment is not necessary.

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

Overdose Effects:

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

Contraindications:

Azee 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.

Precautions:

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 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 Effects:

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, cetirizine, 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.

Storage Conditions:

Store below 30°C temperature, dry place and away from light. Keep all medicine out of the reach of children.

How supplied:

Azee 500 tablet: Each Box containing 2x6's tablets in Alu-Alu blister packs.