

**Composition:**

**Azee PFS-35 ml:** After reconstitution each 5 ml suspension contains Azithromycin Dihydrate USP equivalent to Azithromycin 200 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 pneumoniae.
- 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 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 gonorrhoea.
- Genital ulcer disease due to Haemophilus ducreyi (chancroid).

**Dosage and Administration:**

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

**Children dosage schedule:**

The recommended dose of Azee (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 Azee-PFS) once daily for 3 days
26-35 kg (8-11 years)	300 mg (7.5 ml Azee-PFS) once daily for 3 days
36-45 kg (12-14years)	400 mg (10 ml Azee-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<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.

**Direction for reconstitution of Azee-PFS:**

Shake the bottle until all powder flows freely, add 25 ml (5 teaspoonfull) boiled & cool water for Azee PFS-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 14 days (Azee PFS-35 ml PFS) when stored in a refrigerator.

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