Azithromax

Azithromycin

Composition
Azithromax 500 mg Tablet: Each film coated tablet contains Azithromycin USP 500 mg.
Azithromax Powder for Suspension: Each 5 ml reconstituted suspension contains Azithromycin USP 200 mg.

Pharmacology
Azithromax is an azalide antibiotic, subclass of the macrolide class of antibiotics. **Azithromax** acts by binding to the 50s ribosomal subunit of susceptible organisms and thus interferes with microbial protein synthesis. **Azithromax** demonstrated activity in vitro, against a wide range of Gram-positive and Gram-negative bacteria including: *Staphylococcus aureus, Streptococcus pneumoniae, Streptococcus pyogenes* (Group A) and other *Streptococcal species, Haemophilus influenza* and *parainfluenzae, Moraxella catarrhalis, anaerobes* including *Bacteroides fragilis, Escherichia coli, Bordetella pertussis, Bordetella parapertussis, Borrelia burgdorferi, Haemophilus ducreyi, Neisseria gonorrhoeae* and *Chlamydia trachomatis.* **Azithromax** also demonstrates activity in vitro against *Legionella pneumophila, Mycoplasma pneumoniae* and *hominis, Campylobacter sp., Toxoplasma gondii* and *Treponema pallidum.*

Indications
Azithromax is indicated for infections (caused by susceptible organisms) in lower respiratory tract infections including bronchitis and pneumonia, in upper respiratory tract infections including sinusitis and pharyngitis / tonsillitis, in otitis media and in skin and soft tissue infections. In sexually transmitted diseases in men and women, **Azithromax** is indicated in the treatment of non-gonococcal urethritis and cervicitis due to Chlamydia trachomatis.

Dosage & Administration
Azithromax tablet and suspension should be taken at least 1 hour before or 2 hours after meal. However, **Azithromax** 500 tablet can be taken with or without food. *Adults:* For lower respiratory tract infections including bronchitis and pneumonia, upper respiratory tract infections including sinusitis and pharyngitis/tonsillitis, otitis media and skin and soft tissue infections, the total dose of **Azithromax** is 1.5 gm given as 500 mg once daily for 3 days. An alternative to this dosage schedule is that 500 mg once daily on day 1, followed by 250 mg once daily for next 4 days. For sexually transmitted diseases caused by Chlamydia trachomatis, the dose of **Azithromax** is 1 gm given as a single dose. Alternatively, 500 mg once daily on day 1, followed by 250 mg once daily for next 2 days may also be given. For the treatment of cholera caused by Vibrio cholerae, the dose of **Azithromax** is 1 gm as a single dose. For the treatment of uncomplicated gonorrhea (urethritis or cervicitis) caused by Neisseria gonorrhoeae, a single 2 g dose of **Azithromax** may be given. Taking the dose with food may minimize adverse effects. For non-gonococcal urethritis, shigella infection, traveler's diarrhea, the usual oral dosage is 1 gm administered as a single dose. For typhoid fever caused by susceptible salmonella, the dose is 500 mg once daily for 7 days. Use in the elderly: Normal adult dosage is recommended.
Children: The dose of **Azithromax** in children over 6 months of age is 10 mg/kg body weight once daily for 3-5 days. Alternatively, 10 mg/kg on day 1, followed by 5 mg/kg for next 4 days is also recommended. Safety and effectiveness in the treatment of children under 6 months of age have not been established. For children the dose of **Azithromax** suspension is as follows:

Body weight (age)	Dose	Dosage & Duration
15-25 kg (3-7 years)	200 mg	5 ml daily for 3-5 days
26-35 kg (8-11 years)	300 mg	7.5 ml daily for 3-5 days
36-45 kg (12-14 years)	400 mg	10 ml daily for 3-5 days

For children having body weight over 45 kg, normal adult dosage is recommended.

Direction for reconstitution
To reconstitute **Azithromax** 15 ml powder for suspension, add 10 ml of supplied diluent to the content of the bottle and shake well to mix uniformly.
To reconstitute **Azithromax** 35 ml powder for suspension, add 25 ml of supplied diluent to the content of the bottle and shake well to mix uniformly.
To reconstitute **Azithromax** 50 ml powder for suspension, add 35 ml of supplied diluent to the content of the bottle and shake well to mix uniformly.

Contraindications
Azithromycin is contraindicated in patients with a known hypersensitivity to Azithromycin or any of the macrolide antibiotics.

Precautions
Because of the theoretical possibility of ergotism, Azithromycin and ergot derivatives should not be co-administered. As liver is the principal route of excretion of Azithromycin, it should not be used in patients with hepatic disease. Avoid concomitant administration with terfenadine or astemizole. Precaution should be taken in patients with more severe renal impairment.

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 are reversible upon discontinuation of therapy.

Overdosage
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.

Drug Interactions
Antacids: Peak serum levels but not the total extent of absorption are reduced by aluminium and magnesium containing antacids in the stomach. Azithromycin should therefore be taken at least 1 hour before or 2 hours after taking these antacids.
Ergot Derivatives: Because of the theoretical possibility of ergotism, concomitant administration of ergot derivatives and Azithromycin should be avoided.
Digoxin & Cyclosporin: Macrolides have been known to increase the plasma concentration of Digoxin & Cyclosporin. So, caution should be exercised while co-administration is necessary.

Use in Pregnancy and Lactation
Recent clinical studies have recommended that Azithromycin should be considered for the initial treatment of chlamydial cervicitis in pregnancy. In other infections, Azithromycin should be used only when clearly needed. It is not known whether Azithromycin is excreted in breast milk. Exercise caution when administering to a nursing woman.

Storage
Store in a cool and dry place, protected from light. Any unused portion of reconstituted **Azithromax** suspension should be discarded after 14 days.

Packaging
Azithromax 500 mg Tablet: Each carton contains 2×5's tablet in Alu-Alu blister pack.
Azithromax Powder for Suspension: Each carton contains a bottle containing Azithromycin dry powder for reconstituting 15 ml or 35 ml or 50 ml of suspension and a bottle containing diluent along with a measuring cup, a spoon and a dropper.

Manufactured by
ZISKA PHARMA
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