Zimax®

Azithromycin USP

COMPOSITION:
Zimax® 250 Capsule : Each capsule contains Azithromycin USP 250 mg as Azithromycin Dihydrate USP. **Zimax**® 250 tablet: Each film coated tablet contains Azithromycin USP 250 mg as Azithromycin Dihydrate USP. **Zimax**® 500 tablet : Each film coated tablet contains Azithromycin USP 500 mg as Azithromycin Dihydrate USP. **Zimax**® 15, 30 & 50 ml Dry Powder for Suspension: When reconstituted, each 5 ml suspension contains Azithromycin USP 200 mg as Azithromycin Dihydrate USP. **Zimax**® 500 Infusion: Each vial contains Azithromycin USP 500 mg as lyophilized powder of Azithromycin Dihydrate USP for intravenous infusion.

PHARMACOLOGY:
Zimax® is an azalide antibiotic, subclass of the macrolide class of antibiotics. **Zimax**® acts by binding to the 50s ribosomal subunit of susceptible organisms and thus interferes with microbial protein synthesis. **Zimax**® 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 influenzae* and *parainfluenzae; Moraxella catarrhalis;* anaerobes including *Bacteroides fragilis, Escherichia coli, Bordetella pertussis, Bordetella parapertussis, Borrelia burgdorferi, Haemophilus ducreyi, Neisseria gonorrhoeae* and *Chlamydia trachomatis*. **Zimax**® also demonstrates activity in vitro against *Legionella pneumophila, Mycoplasma pneumoniae* and hominis; Campylobacter sp., *Toxoplasma gondii* and *Treponema pallidum.*

INDICATION:
Zimax® 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, **Zimax**® is indicated in the treatment of non-gonococcal urethritis and cervicitis due to *Chlamydia trachomatis*.

DOSAGE & ADMINISTRATION:
Zimax® can be taken with or without food. To reconstitute **Zimax**® 15, 30, 50 ml powder for suspension, add 10, 20, 35 ml or 2, 4, 7 teaspoonful of just boiled and cooled water to the content of the bottle and shake well to mix uniformly.

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

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 **Zimax**® 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 **Zimax**® 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.
Use in the elderly: Normal adult dosage is recommended.
Children: The dose of **Zimax**® in children over 6 months of age is 10 mg/kg body weight once daily for 3 days. Alternatively, 10 mg/kg on day 1, followed by 5 mg/kg for next 4 days is also recommended. There is no information on use of Azithromycin on children under 6 months of age. For children the dose of **Zimax**® suspension is as follows:

CONTRAINDICATION & PRECAUTION:
Azithromycin is contraindicated in patients with a known hypersensitivity to Azithromycin or any of the macrolide antibiotics. Because of the theoretical possibility of ergotism, Azithromycin and ergot derivatives should not be co-administered. As the 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 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.

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

DRUG INTERACTION:
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 and so caution should be exercised while co-administration is necessary. *Antihistamines*: A potentially life threatening interaction between erythromycin and Terfenadine or Astemizole have been reported. Although such an interaction with Azithromycin is not established yet, it is wise to avoid concomitant use of Azithromycin and Terfenadine or Astemizole.

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.

PHARMACEUTICAL PRECAUTION:
Zimax® capsule, tablet and dry powder for suspension should be stored at room temperature (below 30° C). Any unused portion of reconstituted **Zimax**® suspension should be discarded after 5 days from the date of reconstitution. Keep the medicine away from light and moisture. Keep the medicine out of the reach and sight of children.

HOW SUPPLIED:
Zimax® 250 capsule: Box containing 12 capsules in Alu-Alu blister pack.
Zimax® 250 tablet: Box containing 10 film coated tablets in Alu-Alu blister pack.
Zimax® 500 tablet : Box containing 12 film coated tablets in Alu-Alu blister pack.
Zimax® 15 ml Dry Powder for suspension: Box containing sealed cap HDPE bottle containing dry powder for reconstituting 15 ml suspension with a measuring cup and a dropper.
Zimax® 30 ml Dry Powder for suspension: Box containing sealed cap HDPE bottle containing dry powder for reconstituting 30 ml suspension with a measuring cup and a dropper.
Zimax® 50 ml Dry Powder for suspension: Box containing sealed cap HDPE bottle containing dry powder for reconstituting 50 ml suspension with a measuring cup and a dropper.
Zimax® 500 Infusion: Box contains one vial containing 500 mg sterile lyophilized Azithromycin powder accompanied by 250 ml 0.9% Sodium Chloride (**Solo**™), one infusion set with butterfly needle and 5 ml sterile disposable syringe.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH