

Zitrex

Azithromycin USP

COMPOSITION:

Zitrex 500 mg Tablet: Each film-coated tablet contains Azithromycin 500 mg (as Azithromycin Dihydrate USP).

Zitrex 20 ml PFS: Each 5 ml suspension contains Azithromycin 200 mg (as Azithromycin Dihydrate USP).

Zitrex 35 ml PFS: Each 5 ml suspension contains Azithromycin 200 mg (as Azithromycin Dihydrate USP).

Zitrex 50 ml PFS: Each 5 ml suspension contains Azithromycin 200 mg (as Azithromycin Dihydrate USP).

PHARMACOLOGY:

Azithromycin is an azalide antibiotic, a subclass of the macrolide antibiotics. It acts by binding to the 50s ribosomal subunit of susceptible organisms and thus Interferes with microbial protein synthesis. Azithromycin has been shown to be active against most strains of the following microorganisms, both in vitro and in clinical infections:

Gram-positive microorganisms: *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*.

Gram-negative microorganisms: *Haemophilus ducreyi*, *Haemophilus influenzae*, *Moraxella catarrhalis*, *Neisseria gonorrhoeae*, *Escherichia coli*.

Other microorganisms: *Chlamydia pneumoniae*, *Chlamydia trachomatis*, *Mycoplasma pneumoniae*, *Bacteroides fragilis*, *Legionella pneumophila*, *oxoplasma gondii*.

INDICATIONS:

Zitrex (Azithromycin) is indicated for infections caused by susceptible organisms, In upper respiratory tract infections Including sinusitis, pharyngitis and tonsillitis, In lower respiratory tract Infections Including bronchitis, and pneumonia, skin and soft tissue infections, and otitis media. **Zitrex** (Azithromycin) is Indicated for pelvic Inflammatory disease. **Zitrex** (Azithromycin) is Indicated In the treatment of uncomplicated genital infections due to *Chlamydia trachomatis*.

DOSAGE & ADMINISTRATION:

Infections	Dose	Duration of Therapy
Typhoid/Paratyphoid	Adult: 500 mg once daily Child: 20 mg/kg once daily	7 Days
Shigellosis	Adult: 1 to 1.5 g once daily Child: 20 mg/kg once daily	1 – 5 days
Diarrhoea	Adult: 1 to 1.5 g once daily Child: 20 mg/kg once daily	As required
Cholera	Adult: 1 g once daily Child: 20 mg/kg once daily	As required
Inflammatory bowel disease	Adult: 1 g once daily Child: 20 mg/kg once daily	3 Days
Skin / Skin Structure infections	Adult: 500 mg once daily Child: 10 mg/kg once daily	3 Days
Dental infection	Adult: 500 mg once daily Child: 10 mg/kg once daily	3 Days
Respiratory Tract Infections	Adult: 500 mg once daily Child: 10 mg/kg once daily	3 Days
Eye Infection (Trachoma)	Adult: 1 g as a single dose Child: 20 mg/kg once daily	-
Bacterial STD	2 g as a single dose (should be given to patient plus his/her partner)	-
Acne	500 mg once daily for 3 days then 4 days interval	12 wks

CONTRAINDICATIONS: 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.

SIDE EFFECTS:

Zitrex (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. Reversible elevations in liver transaminases have been seen with a frequency similar to the comparative macrolides and penicillins used in clinical trials. Transient mild reductions in neutrophil counts have occasionally been observed in clinical trials, although a causal relationship to azithromycin has not been established.

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PRECAUTIONS:

As with any antibiotic, observation for signs of superinfection with non-susceptible organisms, including fungi, is recommended. No dose adjustment is needed in patients with renal impairment.

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.

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 and so caution should be exercised while co-administration is necessary.

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Anti-Histamines: 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.

OVERDOSE: 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 adopted.

PHARMACEUTICAL PRECAUTION:

It should be stored in a cool and dry place, protected from light and moisture.

HOW SUPPLIED:

Zitrex 500 mg Tablet: Each box contains 3 X 4 tablets in Alu-Alu blister pack.

Zitrex 20 ml PFS: Each HDPE bottle containing dry ingredients to make 20 ml suspension with a measuring cup and a dropper.

Zitrex 35 ml PFS: Each HDPE bottle containing dry ingredients to make 35 ml suspension with a measuring cup and a dropper.

Zitrex 50 ml PFS: Each HDPE bottle containing dry ingredients to make 50 ml suspension with a measuring cup and a dropper.

Manufactured by



MEDICON Pharmaceuticals Ltd.
Mirpur, Dhaka, Bangladesh.