

ZITHROPYX

Azithromycin for Oral Suspension USP 200 mg / 5 ml

Composition :

Each 5ml (after reconstitution) contains : Azithromycin Dihydrate USP

Eq. to Azithromycin base 200 mg

Excipients : Q.S.

Colour : Sunset yellow FCF

CLINICAL PHARMACOLOGY :

Following oral administration, Zithropyx [Azithromycin] is rapidly absorbed and well distributed throughout body. Rapid distribution of Zithropyx [Azithromycin] into tissues and high concentration within cells results in significantly higher Zithropyx [Azithromycin] concentration in tissues than in plasma or serum.

MODE OF ACTION :

Zithropyx [Azithromycin] acts by binding to 50 S ribosomal subunit of susceptible microorganism and thus interfering with microbial protein synthesis. Nucleic acid synthesis is not affected.

INDICATION & USAGE :

Treatment of mild to moderate infection caused by susceptible strains of microorganism in the following cases :

- Acute bacterial exacerbation of chronic obstructive pulmonary disease.
- Community-acquired pneumonia - in patient appropriate for outpatient oral therapy.
- Pharyngitis and tonsillitis.
- Skin: uncomplicated skin & skin structure infection
- Sexually transmitted diseases: urethritis (non-gonococcal urethritis and cervicitis. - Acute otitis media.

ADVERSE REACTIONS :

G.I.T., diarrhea, loose stool, nausea, abdominal pain, dyspepsia and flatulence, vomiting, melena and cholestatic jaundice.

Cardiovascular : Palpitation, chest pain.

Genitourinary : monilia, vaginitis and nephritis.

C.N.S. : Dizziness, headache, vertigo, general fatigue,

SKIN : rash and photosensitivity.

WARNING :

Treatment with antibacterial agent alerts the normal flora of the colon and may cause super infection with non-susceptible organism as clostridia, which causes colitis.

* Caution should be taken when giving Zithropyx [Azithromycin] to patients with impaired hepatic function.

* Treatment with Zithropyx [Azithromycin] to patients with impaired renal function must be taken with caution. Stop medication with Zithropyx [Azithromycin] if allergic reaction occurs.

* Pregnant woman are treated with Zithropyx [Azithromycin] if clearly needed.

* Caution should be exercised when giving Zithropyx [Azithromycin] to nursing mothers. "

Should only be used to treat bacterial infections but not viral infections. Example: common cold.

DRUG INTERACTIONS :

*Aluminum and Magnesium -containing antacids must not be taken with Zithropyx [Azithromycin] simultaneously as they reduce the peak serum levels (rate) but not the AUC (extent) of Zithropyx [Azithromycin] absorption. Zithropyx [Azithromycin] must not be taken concomitantly with theophyllin as this leads to increase serum concentration of theophyllin.

* Concurrent use of macrotides and warfarin in clinical practice has been associated with increased anticoagulant effects.

* Careful monitoring of patients is advised when Zithropyx [Azithromycin] is taken concomitantly with :
Digoxin : as it leads to elevated digoxin levels.

Ergotamine : as it leads to acute ergot toxicity.

Triazolam : as it leads to decrease clearance of triazolam.

Drug metabolized by cytochrome P450: as it leads to increase serum concentration of these Drug.

CONTRA INDICATIONS :

Zithropyx [Azithromycin] is contraindicated in patients with known hypersensitivity to Azithromycin, Erythromycin or any macrolide.

DOSAGE & ADMINISTRATION :

As directed by the Physician.

DIRECTION FOR USE :

Shake bottle to loosen powder, twist & open the vial of sterile water given with the pack. Slowly add sterile water upto ring on the bottle, put the cap & shake the bottle vigorously. Adjust upto the mark. Content to be consumed within 7 days.

Keep medicines out of reach of children.

Storage :

Store in cool & dry place Protect from light & moisture.

Packing :

30 ml plastic bottle, with sterile water vials.