

Zimax®

Azithromycin Macrolide Antibiotic

COMPOSITION :

Zimax is a nitrogen-containing macrolide or azalide, derived from the macrolide class of antibiotics.

Zimax capsules:

Each capsule contains: Azithromycin dihydrate equivalent to 250 mg azithromycin.

Zimax powder for oral suspension:

Zimax suspension contains sweet banana, strawberry and vanilla flavour.

200mg/5ml : When reconstituted as directed, each 5ml contains : Azithromycin dihydrate equivalent to 200mg Azithromycin.

300mg/7.5ml : When reconstituted as directed, each 7.5ml contains : Azithromycin dihydrate equivalent to 300mg Azithromycin.

INDICATIONS:

Zimax is indicated for the following infections caused by susceptible organisms:

- * Upper respiratory tract infections.
- * Lower respiratory tract infections.
- * Otitis media and sinusitis.
- * Skin & soft tissue infections.
- * **Zimax** is also indicated in the treatment of uncomplicated genital chlamydial infections.

ACTIONS:

Oral bio-availability is 37%. Maximum plasma concentration is achieved within 2 - 3 hours after the administration. **Zimax** is widely distributed throughout the body.

After a single dose of 500mg; **Zimax** concentration in target tissues such as the lungs, tonsils, and prostate exceeds MIC 90 for likely pathogens.

Studies have shown markedly higher azithromycin levels in tissue than in plasma (up to 50 times the maximum observed concentration in plasma) indicating that the drug is highly tissue bound.

Zimax is active against a wide range of Gram-positive and Gram-negative organisms.

Zimax also demonstrates in vitro activity against *Legionella pneumophila*, *Mycoplasma pneumoniae* and *hominis*, *Campylobacter* sp., *Toxoplasma gondii* and *Treponema pallidum* and *Mycobacterium Avium* Complex (MAC).

DOSEAGE & ADMINISTRATION:

CAPSULES :

Zimax capsules should be administered as a single daily dose with a full glass of water taken at least 1 hour before or 2 hours after food to maximize absorption.

Adults:

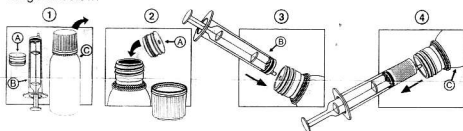
For Sexually transmitted diseases caused by Chlamydia trachomatis the dose is 1gm i.e. 4 capsules given as a single dose. For all other indications, the total dose is 1.5 gm which should be given as 500 mg daily for 3 days.

Use in elderly: Normal adult dosage is recommended.

SUSPENSION :

Use in children: Zimax powder for oral suspension is available for children of body weight less than 45 kg and the recommended dose is 10mg/kg as single daily dose for 3 days. Information on children of age less than six months is not available.

Children up to 15 kg: Measure the dose as closely as possible using the adaptor (A) and syringe (B) provided with the bottle and as explained in the diagram below.



Children weighing more than 15 kg: **Zimax** suspension shall be administered as per the following table, using the adaptor and syringe provided with the bottle.

15 to 25 kg (3-7 years)	5 ml (200 mg), once daily for 3 days.
26 to 35 kg (8-11 years)	7.5 ml (300 mg), once daily for 3 days.
36 to 45 kg (12-14 years)	10 ml (400 mg), once daily for 3 days.
Over 45 kg	As per adult dosage

CONTRA-INDICATIONS:

Zimax is contra-indicated in patients with a known hypersensitivity to azithromycin or any of the macrolide antibiotics.

Because of the theoretical possibility of ergotism, **Zimax** and ergot derivatives should not be co-administered.

Zimax is contra-indicated in patients with hepatic impairment.

PRECAUTIONS AND WARNINGS:

As with erythromycin and other macrolides, rare serious allergic reactions, including angioneurotic oedema and anaphylaxis, have been reported. Some of these reactions with **Zimax** have resulted in recurrent symptoms and required a longer period of observation and treatment.

As with any antibiotic, observation for signs of superinfection with non susceptible organisms, including fungi is recommended.

Use in renal impairment: No dose adjustment is needed in patients with mild renal impairment (creatinine clearance >40 ml/min), but there are no data

regarding **Zimax** usage in patients with more severe renal impairment, thus caution should be exercised in using **Zimax** in these patients.

Use during pregnancy and lactation:

Use in pregnancy: **Zimax** should be used during pregnancy only if adequate alternatives are not available.

Use in lactation: No data on secretion of **Zimax** in breast milk are available, so that **Zimax** should only be used in lactating women where adequate alternatives are not available.

DRUG INTERACTIONS:

Antacids: In patients receiving **Zimax** and antacids, **Zimax** should be taken at least 1 hour before or 2 hours after the antacid.

Carbamazepine: Plasma concentration increased by Azithromycin.

Cimetidine: A single dose of cimetidine administered 2 hours before **Zimax** had no effect on the pharmacokinetics of azithromycin.

Cyclosporin: Some of the related macrolide antibiotics interfere with the metabolism of cyclosporin. In the absence of pharmacokinetic studies or clinical data investigating a potential interaction between **Zimax** and cyclosporin, caution should be exercised before co-administration of these two drugs. If co-administration is necessary, cyclosporin levels should be monitored and the dose adjusted accordingly.

Digoxin: No interactions have been reported in patients who have received concomitant **Zimax** and cardiac glycosides. However, some of the macrolide antibiotics have been reported to impair the metabolism of digoxin (in the gut) in some patients. Therefore, in patients receiving concomitant **Zimax** and digoxin the possibility of raised digoxin levels should be borne in mind.

Ergot derivatives: Because of the theoretical possibility of ergotism, **Zimax** and ergot derivatives should not be co-administered.

Methylprednisolone: In a pharmacokinetic interaction study in healthy volunteers, **Zimax** had no significant effect on the pharmacokinetics of methylprednisolone.

Theophylline: Since interactions between theophylline and some macrolides have been described, patients should be monitored regarding typical reactions of increased theophylline levels when azithromycin and theophyllines are co-administered.

There is no evidence of any pharmacokinetic interaction when **Zimax** and theophylline are co-administered to healthy volunteers.

Warfarin: In a pharmacodynamic interaction study, **Zimax** did not alter the anticoagulant effect of a single 15 mg dose of warfarin administered to healthy volunteers. **Zimax** and warfarin may be co-administered, but monitoring of the prothrombin time should be continued as routinely performed.

Pimozide: Avoid use with pimozide due to risk of cardiotoxicity.

SIDE-EFFECTS:

Zimax is well tolerated with a low incidence of side-effects. Most side-effects observed were mild to moderate in severity.

The majority of side-effects were gastrointestinal in origin with nausea, abdominal discomfort (pain/cramps), vomiting, flatulence, diarrhoea and loose stools being occasionally observed.

Allergic reactions such as rash have occurred and there have also been rare reports of serious hypersensitivity reactions - see 'Precautions and Warnings'. Other side effects include dizziness; drowsiness; headache; photosensitivity; mild hepatitis; and mild neutropenia.

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 **Zimax** has not been established.

OVERDOSAGE:

There are no data on overdosage with **Zimax**. Typical symptoms of overdosage with macrolide antibiotics include hearing loss, severe nausea, vomiting and diarrhoea. Gastric lavage and general supportive measures are indicated.

PRESENTATIONS:

Zimax is available as :

- 250 mg Capsules
- Powder for Oral Suspension 200 mg/5 ml and 300mg/7.5ml.

This is a medication

- A Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of use of the pharmacist who sold the medication.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of the reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

Manufactured by **SPIMACO**
Al-Qassim Pharmaceutical Plant
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Medical Appliances Corporation
Saudi Arabia

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