ZITHROMAX*

AZITHROMYCIN

Composition

Zithromax (Azithromycin) is an Azalide, a sub class of Macrolide antibiotics, for oral administration.
Each capsule contains:
Active Ingredients
262.05 mg of azithromycin dihydrate equivalent to 250 mg of azithromycin.
Inactive Ingredients
Lactose, maize starch, magnesium stearate, sodium lauryl sulphate, titanium dioxide, gelatin.

Indications

The antimicrobial spectrum of activity of azithromycin covers the following organisms:
Gram-positive aerobic bacteria: Staphylococcus aureus, Streptococcus pyogenes (group A betahaemolytic streptococci), Streptococcus pneumoniae, alpha-haemolytic streptococci (viridans group) and other streptococci, and Corynebacterium diphteriae. Azithromycin demonstrates cross-resistance with erythromycin-resistant gram-positive strains including Streptococcus faecalis (enterococci) and most strains of methicillin-resistant staphylococci.
Gram-negative aerobic bacteria: Haemophilus influenzae and parainfluenzae, Moraxella catarrhalis, Acinetobacter species, Yersinia species, Legionella pneumophila, Bordetella pertussis and parapertussis, and Plesiomonas shigella species, Pasteurella species, Vibrea cholerae and parahaemolyticus. Activity against Escherichia coli, Sallmonella enteritidis and typhi, Enterobacter species, Aeromonas hydrophila, and Klebsiella species is variable, therefore, susceptibility testing should be performed.
Proteus species, Serratia species, Morganella species, and Pseudomonas aeruginosa are usually resistant.
Anaerobic bacteria: Bacteroides fragilis and Bacteroides species, Clostridium perfringens, Peptococcus and Peptostreptococcus species, Fusobacterium necrophorum and Propionibacterium acnes.
Micro-organisms causing sexually transmitted diseases: Chlamydia trachomatis, Treponema pallidum, Neisseria gonorrhoea, and Haemophilus ducreyi.
Other micro-organisms: Borrelia burgdorferi (Lyme Disease), Chlamydia pneumoniae (TWAR), Toxoplasm gondii, Mycoplasma pneumoniae and hominis, Ureaplasma urealyticum, Pneumocystis carnii, Mycobacterium avium, Campylobacter species, and Listeria monocytogenes.
Zithromax is clinically indicated in particular in infections caused by azithromycin susceptible pathogens such as:

- infections of the upper respiratory tract including sinusitis, pharyngitis, tonsillitis. (Azithromycin is not the drug of first choice for the treatment of tonsillitis or pharyngitis due to streptococci or for the prophylaxis of rheumatic fever. So far, there are no epidemiologic long-term studies of the efficacy of such a prophylaxis or of the frequency of possible late sequelae after 5-day therapy).
- infections of the lower respiratory tract including bronchitis and pneumonia.
- otitis media.
- infections of skin and soft tissues.
- uncomplicated genital infections caused by Chlamydia trachomatis or Neisseria gonorrhoea (non multi-resistant strains); concurrent use in Trepanoma Pallidium should be excluded.

Contraindications

Contraindications are diseases or conditions in which certain drugs must not be taken or may be used only after careful consideration by the physician as the anticipated benefit in such cases is generally out of proportion to the possible damage. Contraindications may also occur or become known only after treatment with this drug has started. In these cases too, your physician should be informed.
Zithromax is contraindicated in patients with a known hypersensitivity to azithromycin or macrolide antibiotics such as erythromycin.
Zithromax should not be used in patients with severe hepatic diseases, as it is mainly excreted via the liver. At present, conclusive evidence as to the safety of Zithromax usage in such patients is not yet available.
In high dose preclinical studies, azithromycin has been noted to cause reversible phospholipidosis. There is no evidence that this is of relevance to the normal use of azithromycin in humans.

Drug Interactions

The effects of some drugs can be influenced by concomitant use of other drugs. You should therefore consult your physician if you are taking other drugs regularly, have recently used other drugs, or if you wish to use them concomitantly with this drug. Your physician will be able to tell you whether intolerance can be expected under these circumstances, or whether special measures are necessary if you take this drug.
Azithromycin/Antacids or Gastric Acid Secretion Inhibitors:
Mineral antacids should not be taken simultaneously with Zithromax as a study revealed peak serum levels reduced by up to 30%. Therefore, a time interval of 2-3 hours should be observed. However, the extent of absorption (parameter: AUC) was not lowered.
Cimetidine had no influence on the speed and extent of absorption of azithromycin. Therefore, it can be co-administered with Zithromax.
Azithromycin/Ergot Alkaloids:
Although no experience is available so far, vasoconstricting effects with circulatory disorders in particular of fingers and toes cannot be excluded if Zithromax and dihydroergotamine or non-hydrated ergot alkaloids are administered concomitantly. Therefore, concomitant administration should be avoided for safety reasons.
Azithromycin/Theophylline:
Neither pharmacokinectic nor clinical studies have revealed any evidence of interactions with 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.
Azithromycin/ Miscellaneous Other Drugs:
Macrolide-antibiotics are known to interact with triazolam, cyclosporin, and digoxin. For Zithromax, sufficient data are not available but the possibility of interactions should be borne in mind.
In studies with healthy subjects, co-administration of azithromycin did not affect carbamazepine serum leves significantly and its active metabolite was not also influenced. Likewise, there was no significant mutual influence for methyl-prednisolone.

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Azithromycin/Other Antibiotics:
The potential of parallel resistance between azithromycin and macrolide antibiotics (e.g. erythromycin) as well as lincomycin, and clindamycin should be borne in mind. Therefore, co-administration of serveral drugs of this class is not recommended.

Dosage, Mode and Duration of Administration

Adults including elderly patients and juveniles weighing more than 45 kg body weight (BW) usually receive a total dose of 1.5 g of azithromycin. For the treatment of sexually transmitted diseases caused by Chlamydia trachomatis or susceptible Neisseria gonorrhoea the dose is 1 g of azithromycin taken as a single oral dose.
Zithromax powder for oral suspension is available for children with a body weight less than 45 kg.
Unless otherwise prescribed, the dosage recommendations in adults and children with a body weight over 45 kg are as follows:
3-day therapy:
500 mg of azithromycin daily, i.e. 2 capsules once daily for three days.
Alternative 5-day therapy:
1st day 1 x 500 mg of azithromycin, i.e. 2 capsules
2nd day 1 x 250 mg of azithromycin, i.e. 1 capsule
3rd day 1 x 250 mg of azithromycin, i.e. 1 capsule
4th day 1 x 250 mg of azithromycin, i.e. 1 capsule
5th day 1 x 250 mg of azithromycin, i.e. 1 capsule
The efficacy of a 5-day regimen of azithromycin in the treatment of patients with pneumonia is sufficient in most cases.
Sexually transmitted disease:
1 g of azithromycin once, i.e. 4 capsules once.
No dosage adjustment is required in patients with impaired renal function up to a creatinine of ≥ 40 ml/min.
Zithromax should be administered at least 1 hour before or, at the earliest, 2 hours after food.
Zithromax may be administered to pregnant and nursing women only in lifethreatning conditions or when alternative treatment is not possible, as a final assesment of the safety of this therapy is not possible yet.
Because of an existing cross-resistance to erythromycin-resistant gram-positive strains and most strains of methicillin-resistant staphylococci Zithromax should not be used in these cases.
Caution should be excerised when using Zithromax in patients with severe renal insufficiency (creatinine clearance < 40 ml/min) as it has only been established that no dose reduction is required in mild renal insufficiency (creatinine clearance ≥ 40 ml/min).

Adverse Reactions

In additions to the desired main effects, drugs can also produce adverse effects, so-called side effects. The following side effects linked in time with the administration of Azithromycin have been observed, though they do not necessarily occur in all patients:
Gastrointestinal Tract:
Disorders in the form of diarrhoea and loose stools, abdominal complaints pain, spasms), nausea, vomiting, and flatulence may occasionally occur. In patients with severe and persistent diarrhoea, the possibility of life-threatening pseudomembraneous colitis should be borne in mind. In such cases, Zithromax treatment should be immediately terminated and appropriate therapy (e.g. with oral vancomycin 4 x 250 mg/day) instituted. Self-medication with hypoperistaltic drugs should be avoided.
Hepatobiliary System:
A reversible increase in liver enzymes(transminases, alkaline phosphatase) and in serum bilirubin were rarely observed.
Blood and Blood Corpuscles
Blood count chances (neutropenia) were observed in individual cases.
Hypersensitivity Reactions:
Hypersensitivity reactions are rare during Zithromax treatment. They include reactions of the skin and mucosa such as reddening with or without pruritus. As with erythromycin and other macrolides severe allergic reactions including reversible local swellings of skin, mucosa or joints (angioedema) and acute allergic general reactions (anaphylaxis) have been reported in rare cases during azithromycin treatment.
Miscellaneous:
As with any antibiotic preparation, observation for signs of superinfection with non-susceptible organisms, including fungi is recommended and appropriate therapy should be instituted, if necessary.
The capsules should be swallowed whole with some liquid.

Note:

Zithromax should not be used after the expiry date printed on the package.
Keep drugs out of the reach of children

Properties

Azithromycin differs from other antibiotics as to its high tissue affinity. The tissue concentrations exceed those in plasma up to 50 times and the tissue half-lives range between 2 and 4 days. Therefore, the dosage regimen for Zithromax differs from that of other antimicrobials.

How Supplied

- Zithromax Capsules 250 mg packs of 4 and 6
- Zithromax powder for oral suspension 200 mg / 5 ml packs of 15 ml, 22.5 ml and 30 ml

Date of last revision of package insert: October 19, 1995
Manufactured by PFIZER ITALIA S.r.l., Latina, Italy.

This is a medicament

– Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
– Follow strictly the doctors's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
– The doctor and the pharmacist are experts in medicine, its benefits and risks.
– Do not by yourself interrupt the period of treatment prescribed for you.
– 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