

Eradecin®

Azithromycin

COMPOSITION: Eradecin (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 beta-haemolytic streptococci), *Streptococcus pneumoniae*, alpha-haemolytic streptococci (viridans group) and other streptococci, and *Corynebacterium diphtheriae*. 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, *Vibrio cholerae* and parahaemolyticus. Activity against *Escherichia coli*, *Salmonella 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), *Toxoplasma gondii*, *Mycoplasma pneumoniae* and *hominis*, *Ureaplasma urealyticum*, *Pneumocystis carinii*, *Mycobacterium avium*, *Campylobacter* species, and *Listeria monocytogenes*.

Eradecin 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 *Treponema Pallidum* 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.

Eradecin is contraindicated in patients with a known hypersensitivity to azithromycin or macrolide antibiotics such as erythromycin.

Eradecin 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 Eradecin 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 Azomax 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 Azomax.

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 Azomax and dihydroergotamine or non-hydrated ergot alkaloids are administered concomitantly. Therefore, concomitant administration should be avoided for safety reasons.

Azithromycin / Theophylline: Neither Pharmacokinetic 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 Azomax, 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 levels significantly and its active metabolite was not also influenced. Likewise, there was no significant mutual influence for methyl-prednisolone.

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 several 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.

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 capsules
3rd day	1 x 250 mg of azithromycin, i.e. 1 capsules
4th day	1 x 250 mg of azithromycin, i.e. 1 capsules
5th day	1 x 250 mg of azithromycin, i.e. 1 capsules

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.

Eradecin should be administered at least 1 hour before or, at the earliest, 2 hours after food.

Eradecin may be administered to pregnant and nursing women only in life-threatening conditions or when alternative treatment is not possible, as a final assessment 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 Eradecin should not be used in these cases.

Caution should be exercised when using Eradecin 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 addition 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 pseudomembranous colitis should be borne in mind. In such cases, Eradecin 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 (transaminases, alkaline phosphatase) and in serum bilirubin were rarely observed.

Blood and Blood Corpuscles.

Blood count changes (neutropenia) were observed in individual cases.

Hypersensitivity Reactions: Hypersensitivity reactions are rare during Eradecin 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: Eradecin should not be used after the expiry date printed on the package.

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 Azomax differs from that of other antimicrobials.

HOW SUPPLIED: Eradecin capsules 250 mg, 6 per pack.

STORAGE: Store below 30°C.

THIS IS A MEDICAMENT

- A drug is a product which acts on your health and its consumption could be dangerous when you do not follow the instructions.
- Follow strictly the doctor's prescriptions, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist know the 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 out of the reach of children.

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