AZITHROMYCIN

500 mg Tablets

COMPOSITION:
Each film-coated tablet contains:
Azithromycin dihydrate USP
Eq. to anhydrous azithromycin 500 mg
Excipients q.s.
Approved color used.

PHARMACOLOGY: Pharmacodynamics: Azithromycin binds to the 50S ribosomal subunit of susceptible microorganisms and inhibits protein synthesis. It acts as a bactericide at high concentrations.

Pharmacokinetics: Azithromycin is acid-stable and can therefore be administered orally without the need for protection against gastric acid. It is readily absorbed and distributed into most tissues and phagocytes. Due to its high concentration in phagocytes, azithromycin is actively transported to the site of infection. During active phagocytosis, large concentrations of azithromycin are released. Tissue concentrations of azithromycin can be more than 50 times higher than plasma concentrations. This is due to ion trapping and high lipid solubility.

INDICATIONS: Azithromycin is indicated for the treatment of the following infections when known or likely to be caused by one or more susceptible microorganisms: bronchitis, community-acquired pneumonia, sinusitis, pharyngitis/tonsillitis, otitis media, soft tissue infections, and uncomplicated genital infections due to *Chlamydia trachomatis*.

DOSAGE AND ADMINISTRATION: Children weighing over 45 kg and adults, including the elderly: The total dose of azithromycin is 1500 mg, to be administered over three days (500 mg once daily or 250 mg twice daily). For uncomplicated genital infections due to *Chlamydia trachomatis*, the dose is 1000 mg as a single oral dose. Azithromycin tablets are not suitable for children weighing less than 45 kg.

CONTRAINDICATIONS: Azithromycin is contraindicated in patients with known hypersensitivity to azithromycin, any macrolide or ketolide antibiotic, erythromycin, or any excipients.

WARNINGS AND PRECAUTIONS: As with erythromycin and other macrolides, serious allergic reactions, including angioedema and anaphylaxis (rarely fatal), have been reported. Some of these reactions to azithromycin resulted in recurrent symptoms and required a longer period of observation and treatment. Prolonged cardiac repolarization and QT interval, carrying a risk of developing cardiac arrhythmia, have been observed during treatment with other macrolides. A similar effect with azithromycin cannot be completely ruled out in patients at increased risk of prolonged cardiac repolarization.
As with any antibiotic preparation, observation for signs of superinfection with non-susceptible organisms, including fungi, is recommended. There is a possibility of superinfections (e.g., fungal infections) occurring.

Streptococcal infection: Penicillin is generally the first choice for the treatment of pharyngitis/tonsillitis caused by *Streptococcus pyogenes* and also for the prophylaxis of acute rheumatic fever. Azithromycin is generally effective against streptococci in the oropharynx, but no data are available demonstrating the efficacy of azithromycin in preventing acute rheumatic fever.
Use in renal impairment: In patients with severe renal impairment (GFR <10 ml/min), a 33% increase in systemic exposure to azithromycin was observed.

SIDE EFFECTS: Azithromycin is well tolerated, with a low incidence of side effects. Most observed side effects were mild to moderate in severity.
The most common side effects were gastrointestinal discomfort (pain/cramps), vomiting, flatulence, and diarrhea; loose stools were occasionally observed.
Allergic reactions, such as skin rashes, occurred, and there were also rare reports of severe hypersensitivity reactions.
Reversible elevations in liver transaminases were observed with a frequency similar to that of comparator macrolides and penicillins used in clinical trials. Cases of cholestatic jaundice were rarely observed.
Mild, transient reductions in neutrophil counts were occasionally observed in clinical trials, although a causal relationship with azithromycin has not been established.

PREGNANCY AND LACTATION: Use in pregnancy: Animal reproduction studies are insufficient regarding effects on pregnancy, embryonic/fetal development, parturition, and postnatal development. The potential risk to humans is unknown. Azithromycin should not be used during pregnancy unless clearly necessary.
Use in lactation: There is limited or insufficient information regarding the excretion of azithromycin in human or animal breast milk. A risk to the breastfed infant cannot be excluded. The decision to continue or discontinue breastfeeding, or to continue or discontinue azithromycin therapy, should be made taking into account the benefit of breastfeeding to the infant and the benefit of azithromycin therapy to the woman.

DRUG INTERACTIONS: Antacids: In patients receiving azithromycin and antacids, azithromycin should be taken at least 1 hour before or 2 hours after the antacid. Carbamazepine: In a pharmacokinetic interaction study in healthy volunteers, no significant effect was observed on the plasma levels of carbamazepine or its active metabolite.
Cimetidine: A single dose of cimetidine administered 2 hours before azithromycin had no effect on the pharmacokinetics of azithromycin.
Cyclosporine: Some related macrolide antibiotics interfere with the metabolism of cyclosporine. In the absence of pharmacokinetic studies or clinical data investigating the potential interaction between azithromycin and cyclosporine, caution should be exercised before co-administering these two drugs. If co-administration is necessary, cyclosporine levels should be monitored and the dose adjusted accordingly.
Digoxin: Some macrolide antibiotics have been reported to impair the microbial metabolism of digoxin in the intestine in some patients. In patients receiving concomitant azithromycin, a related azalide antibiotic, the possibility of this interaction should be considered and digoxin levels monitored.
Ergotamine derivatives: Due to the theoretical possibility of ergotism, azithromycin and ergotamine derivatives should not be co-administered.
Methylprednisolone: In a pharmacokinetic interaction study in healthy volunteers, azithromycin had no significant effect on the pharmacokinetics of methylprednisolone.
Theophylline: Azithromycin did not affect the pharmacokinetics of theophylline administered as a single intravenous infusion or as multiple oral doses of 300 mg every 12 hours. In general, however, theophylline levels should be monitored.
Warfarin: In a pharmacodynamic interaction study, azithromycin did not alter the anticoagulant effect of a single 15 mg dose of warfarin administered to healthy volunteers. Azithromycin and warfarin may be co-administered, but INR monitoring should be continued as routinely performed.

OVERDOSE: There is no data regarding azithromycin overdose. Typical symptoms of macrolide antibiotic overdose include hearing loss, severe nausea, vomiting, and diarrhea. Gastric lavage and general supportive measures are indicated.

STORAGE: Store in a cool, dark, and dry place below 30ºC.

Keep medicines out of the reach of children.

PRESENTATION: A blister pack of 3 tablets.

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