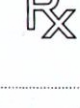
AZITHROMYCIN

PNEUMOZITH

500 mg Film-coated Tablet
Antibacterial (Macrolide)



FORMULATION:
Each film-coated tablet contains:
Azithromycin (as dihydrate).....500 mg

PRODUCT DESCRIPTION:
Azithromycin 500 mg film-coated tablet is a white to off-white, oblong, biconvex, bisected on one side and plain on the other side.

PHARMACODYNAMICS:
Pharmacotherapeutic group: Macrolides, ATC code J01FA

Azithromycin is the first class of antibiotics designated chemically as azalides. Chemically it is derived by insertion of a nitrogen atom into the lactone ring of erythromycin A. The chemical name of azithromycin is 9-deoxy-9a-aza-9a-methyl-9a-homoerythromycin A. The molecular weight is 749.0

The mode of action of azithromycin is inhibition of protein synthesis in bacteria by binding to the 50s ribosomal subunit and preventing translocation of peptides.

Azithromycin demonstrates activity in vitro against a wide range of bacteria including:

Gram-positive Aerobic Bacteria - *Staphylococcus aureus*, *Streptococcus pyogenes* (group A beta-hemolytic streptococci), *Streptococcus pneumoniae*, alpha-hemolytic streptococci (viridans group) and other streptococci, and *Corynebacterium diphtheriae*. Azithromycin demonstrates cross-resistance with erythromycin-resistant Gram-positive strains, including *Streptococcus faecalis* (enterococcus) and most strains of methicillin-resistant staphylococci.

Gram-negative Aerobic Bacteria - *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Moraxella catarrhalis*, *Acinetobacter* species, *Yersinia* species, *Legionella pneumophila*, *Bordetella pertussis*, *Bordetella parapertussis*, *Shigella* species, *Pasteurella* species, *Vibrio cholerae* and *Parahaemolyticus*, *Plesiomonas shigelloides*. Activities against *Escherichia coli*, *Salmonella enteriditis*, *Salmonella typhi*, *Enterobacter* species, *Aeromonas hydrophila* and *Klebsiella* species are variable and susceptibility tests 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* species and *Peptostreptococcus* species, *Fusobacterium necrophorum* and *Propionibacterium acnes*.

Organism of Sexually Transmitted Diseases - Azithromycin is active against *Chlamydia trachomatis* and also shows good activity against *Treponema pallidum*, *Neisseria gonorrhoeae*, and *Haemophilus ducreyi*.

Other Organisms - *Borrelia burgdorferi* (Lyme disease agent), *Chlamydia pneumoniae*, *Mycoplasma pneumoniae*, *Mycoplasma hominis*, *Ureaplasma urealyticum*, *Campylobacter* species and *Listeria monocytogenes*.

Opportunistic Pathogens Associated with HIV Infections - *Mycobacterium avium-intracellulare* complex, *Pneumocystis carinii* and *Toxoplasma gondii*.

PHARMACOKINETICS:
Azithromycin given orally is rapidly absorbed and about 40% bioavailable. Absorption from capsules, but not tablets or suspension, is reduced by food. Peak plasma concentrations occur 2 to 3 hours after an oral dose and 1 to 2 hours after intravenous dosage. However, azithromycin is extensively distributed into the tissues, and tissue concentrations subsequently remain much higher than those in the blood; in contrast to most other antibacterials, plasma concentrations are therefore of little value as a guide to efficacy. High concentrations are taken up into white blood cells. There is little diffusion into the CSF when the meninges are not inflamed. Data from animal studies indicate that azithromycin crosses the placenta. Small amounts of azithromycin are demethylated in the liver, and it is excreted in bile mainly as unchanged drug and a number of inactive metabolites have also been detected. About 6% of an oral dose (representing about 20% of the amount in the systemic circulation) is excreted in the urine. The terminal elimination half-life is about 68 hours.

INDICATIONS:
Azithromycin is a nitrogen-containing macrolide or azalide with wide spectrum of activity that has been used in the treatment of a wide variety of infections caused by susceptible organisms. It is given in the treatment of respiratory tract infections (including otitis media), in skin and soft-tissue infections, and in uncomplicated genital infections. Azithromycin may also be used for the prophylaxis, and as a component of regimens in the treatment of *Mycobacterium avium* complex (MAC). It is used in some countries for the prophylaxis of endocarditis in at-risk patients unable to take penicillin. It is also used in the management of trachoma and typhoid.

DOSAGE AND ADMINISTRATION:
Usual adult dose: 500 mg as single dose daily for 3 days.
Initial dose: 500 mg followed by 250 mg daily for 4 days.
For uncomplicated genital infections due to *Chlamydia trachomatis*: 1 g as a single dose.
For uncomplicated gonorrhea: 2 g as a single dose.
For prophylaxis of disseminated MAC infections: 1.2 g once weekly.
Or as prescribed by the physician.

CONTRAINDICATIONS:
Contraindicated in patients with known hypersensitivity to azithromycin, erythromycin or any macrolide antibiotics.

PRECAUTIONS:
As with erythromycin and other macrolides, rare serious allergic reactions, including angioedema and anaphylaxis (rarely fatal), have been reported. Some of these reactions with azithromycin have resulted in recurrent symptoms and required a longer period of observation and treatment.

Since liver is the principal route of elimination for azithromycin, the use of azithromycin should be undertaken with caution in patients with significant hepatic disease.

In patients receiving ergot derivatives, ergotism has been precipitated by co-administration of some macrolide antibiotics. There are no data concerning the possibility of an interaction between ergot and azithromycin. However, because of the theoretical possibility of ergotism, azithromycin and ergot derivatives should not be co-administered.

PREGNANCY AND LACTATION:
Animal reproduction studies have been performed at doses up to moderately maternally toxic dose concentrations. In these studies, no evidence of harm to the fetus due to azithromycin was found. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, azithromycin should be used during pregnancy only if clearly needed.

There are no data on secretion in breast milk. As many drugs are excreted in human milk, azithromycin should not be used in the treatment of a lactating woman unless the physician feels that the potential benefits justify the potential risk to the infant.

DRUG INTERACTIONS:
Concurrent administration of antacids containing aluminum or magnesium salts can reduce the rate, but not the extent, of absorption of azithromycin. Azithromycin and ergot derivatives should not be co-administered because of the theoretical possibilities of ergotism. Some of the macrolide antibiotics have been reported to impair the metabolism of Digoxin (in the gut) in some patients. Increased rifabutin toxicity has been reported in patients receiving azithromycin and rifabutin.

ADVERSE DRUG REACTIONS:
Gastrointestinal disturbances are the most frequent effect of azithromycin but are usually mild and less frequent than erythromycin. Headache, somnolence, and taste disturbances may occur. Severe hypersensitivity reactions occur rarely but may be prolonged. Thrombocytopenia and mild transient neutropenia have been rarely reported in patients receiving azithromycin.

Other adverse effects include agranulocytosis, aggravation of muscular weakness in myasthenia gravis patients, and pancreatitis. Prolongation of the CT interval and other arrhythmias, sometimes fatal, including torsades de pointes.

OVERDOSE AND TREATMENT:
Adverse events experienced in higher than recommended doses were similar to those seen at normal doses. In the event of overdosage general symptomatic and supportive measures are indicated as required.

AVAILABILITY:
Aluminum Foil Strip x 3's (Box of 3's)

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph
Patient should seek medical attention immediately at the first sign of any adverse drug reaction.

REGISTRATION NUMBER:
DRP-3549-05

DATE OF FIRST AUTHORIZATION:
February 8, 2021

DATE OF REVISION OF PACKAGE INSERT:
October 2022

STORE AT TEMPERATURES NOT EXCEEDING 30°C.

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