AZITHROMYCIN

ZITHROCIN™

500 mg Tablet

Antibacterial

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

PRODUCT DESCRIPTION:
Azithromycin is an azalide antibiotic, a subclass of macrolide antibiotics. Azalides are distinguished from other macrolides such as erythromycin, by the addition of nitrogen at position 9a of the lactone ring. Azithromycin has a broader spectrum of activity than that of erythromycin or clarithromycin.

PHARMACODYNAMICS AND PHARMACOKINETICS:
Like other macrolides, azithromycin inhibits RNA-dependent protein synthesis by binding to the 50S ribosomal subunit of the 70S ribosome of susceptible bacteria. The site of action appears to be the same as that of the macrolides, clindamycin, lincomycin, and chloramphenicol. Azithromycin is less active than erythromycin against streptococci and staphylococci, but has greater activity in vitro against some Gram-negative organisms such as Haemophilus influenzae and Moraxella catarrhalis (Branhamella catarrhalis), as well as having activity against some of the Enterobacteriaceae such as Escherichia coli, Salmonella and Shigella spp. Azithromycin is also more active than erythromycin against Chlamydia trachomatis and Ureaplasma urealyticum and some opportunistic mycobacteria including Mycobacterium avium complex. Azithromycin is active against the protozoa Toxoplasma gondii and Plasmodium falciparum.

Azithromycin is rapidly absorbed after oral intake and achieves peak plasma concentration in about 2-3 hours. Azithromycin is extensively distributed into the tissues and there is little diffusion into the CSF when the meninges are not inflamed. Excretion is mainly in bile as an unchanged drug it has terminal elimination half-life of about 68 hours.

INDICATIONS:
Azithromycin is indicated for the treatment of the following mild to moderate infections caused by susceptible organisms: such as respiratory tract infections, uncomplicated skin and soft tissue infections, uncomplicated genital infections

chlamydial infections and non-gonococcal urethritis, chancroid, and pelvic inflammatory disease.

DOSAGE AND ADMINISTRATION:
Azithromycin should be administered as a single dose, with or without food.

For all indications other than sexually transmitted diseases, the total dose is 1.5 g, which should be given as 500 mg daily for 3 days. Alternatively, an initial dose of 500 mg may be followed by 250 mg daily for 4 days.

For uncomplicated sexually transmitted disease caused by Chlamydia trachomatis the dose is 1 g given as a single dose. A single dose of
2 g has been given for uncomplicated gonorrhea.

For prophylaxis of disseminated MAC infections, azithromycin 1.2 g maybe given once weekly. For treatment or secondary prophylaxis,
500 mg once daily should be given with other anti-mycobacterials.

For mild to moderate typhoid caused by multidrug resistant strains,
500 mg once daily maybe given for 7 days.

Or as prescribed by the physician.

CONTRAINDICATIONS/PRECAUTIONS/WARNINGS:
Azithromycin is contraindicated in patients with known hypersensitivity to azithromycin, erythromycin or any macrolide antibiotics.

Use of azithromycin should be avoided in patients with severe hepatic impairment because biliary excretion is the major route of elimination for azithromycin. It should also be used with caution in patients with renal impairment.

PREGNANCY AND LACTATION:
Reproduction studies done in animals given azithromycin at doses up to moderately maternally toxic dose have found no evidence of harm to the fetus. There are no adequate and well-controlled studies done in pregnant and nursing women. Azithromycin has been detected in human milk. Caution should be exercised when administering azithromycin to nursing women.

ADVERSE DRUG REACTIONS:
Most frequent adverse effects are gastrointestinal in origin with anorexia, nausea, abdominal discomfort, cramps, flatulence, vomiting and diarrhea. Adverse effects also include pruritus, urticaria, skin rashes as well as occasional cases of anaphylaxis. Stevens-Johnson syndrome and toxic epidermal necrolysis have also been reported very rarely. Thrombocytopenia and mild transient neutropenia have been rarely reported in patients taking azithromycin. Azithromycin may

aggravate muscle weakness in patients with myasthenia gravis. Other side effects reported include chest pain, melena, vaginitis, headache, taste disturbances, vertigo, dizziness, convulsions, somnolence, tinnitus and fatigue.

Azithromycin may cause reversible sensorineural hearing loss, eosinophilia, acute interstitial nephritis. Effects on fluid and electrolyte homeostasis have also been reported.

Azithromycin like other macrolides, may cause irregular heart beat. Patients at particular risk are those with history of existing QT interval prolongation, low blood levels of potassium or magnesium, and those taking certain drugs used to treat arrythmias.

DRUG INTERACTIONS:
Azithromycin may interact with antacids containing aluminum or magnesium salts and should be given at least an hour before or 2 hours after the antacid. Erythromycin and other macrolides have the potential to interact with a large number of drugs through their action on the hepatic cytochrome P450 isoenzymes, particularly CYP1A2 and CYP3A4. These interactions can result in severe adverse effects, including ventricular arrhythmias with astemizole, cisapride and terfenadine. Other macrolides including azithromycin and dirithromycin are reported to have little or no effect on hepatic cytochrome, and consequently may produce fewer drug interactions.

Other mechanisms by which macrolides cause interactions include suppression of the gastrointestinal flora responsible for the intraluminal metabolism of digoxin and possibly oral contraceptives, and the stimulant effect of macrolides on gastrointestinal motility which is believed to be responsible for the interaction between spiramycin and levodopa.

Serum concentrations of azithromycin are markedly increased when it is administered with nelfinavir, but the clinical significance of this is uncertain. Although dosage adjustment is not required the patient should be closely monitored for adverse effects.

Macrolides have been reported rarely to prolong the QT interval and should be used with caution with other drugs known to also have this effect.

Azithromycin may also interact with zidovudine, ergot derivates, coumarin and ciclosporin. Caution should be exercised before considering administration with these drugs.

OVERDOSAGE AND TREATMENT:
Treatment of overdosage is symptomatic and supportive. Dysrhythmias should be treated with appropriate antiarrhythmic drugs.

Gastric lavage and general supportive measures are indicated as required.

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

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

DR-XY34686

STORE AT TEMPERATURES NOT EXCEEDING 30^{O}C.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

Pnsv Asia

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