test (including AST and ALT) and elevated bilirubin. Hepatitis and cholestratic jaunduce, as well as rare cases of hepatic necrosis and hepatic failure (some resulting in death), have been reported during postmarketing experience. Although plasma concentrations may be increased in renal impairment dosage adjustment is not usually required.

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

Warnings

QT prolongation

Prolonged cardiac repolarization and QT interval, imparting a risk of developing cardiac arrhythmia and torsades de pointes, have been seen in the treatment with macrolides, including azithromycin. Cases of torsades de pointes have been spontaneously reported during post marketing surveillance in patients receiving azithromycin. Providers should consider the risk of QT prolongation which can be fatal when weighing the risks and benefits of azithromycin for at risk group including:

- Patients with known prolongation of the QT interval, a history of torsades de pointes, congenital long QT syndrome, bradyarrhythmias or uncompensated heart failure
- Patients on drugs known to prolong the QT interval
- Patients with ongoing proarrhythmic conditions such as uncorrected hypokalemia or hypomagnesemia, clinically significant bradycardia, and in patients receiving Class IA (quinidine, procainamide) or Class III (dofetilide, amiodarone, sotalol) antiarrhythmic agents

Elderly patients may be more susceptible to drug-associated effects on the QT interval

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

Overdosage:
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:
Alu/White PVC-PVdC Blister Pack x 3's (Box of 3's)

Registration Number: DR-XY39058
Date of First Authorization: February 2012
Revision Date: December 2018

STORE AT ROOM TEMPERATURES NOT EXCEEDING 30°C

Manufactured for
Natrapharm, Inc.
The Patriot Building
Km. 18, West Service Road,
South Luzon Expressway,
Parañaque City
by Lloyd Laboratories, Inc.
No. 10 Lloyd Avenue,
First Bulacan Industrial City
City of Malolos, Bulacan

NTAZT500003IN1801

Natrapharm

Azithromycin

Azithro-Natrapharm®

500mg Film-Coated Tablet
Antibacterial

Description:
Azithro-Natrapharm is available as white to off-white film-coated tablet, capsule shaped plain on one side and bisected on the other side packed in alu/white PVC-PVdC blister pack x 3's (box of 3's).

Formulation:
Each fim-coated tablet contains: Azithromycin (as Monohydrate), USP 500mg

Mechanism of Action
Azithromycin usually is bacteriostatic, although the drug may be bactericidal in high concentrations against selected organisms. Bactericidal activity has been observed in vitro against *Streptococcus pyogenes, S. pneumoniae, and Haemophilus influenzae*. Azithromycin inhibits protein synthesis in susceptible organisms by penetrating the cell wall and binding to 50S ribosomal subunits, thereby inhibiting translocation of aminoacyl transfer-RNA and inhibiting polypeptide synthesis. The site of action of azithromycin appears to be the same as that of the macrolides (i.e., erythromycin, clarithromycin), clindamycin, lincomycin, and chloramphenicol. The antimicrobial activity of azithromycin is reduced at low pH. Azithromycin concentrates in phagocytes, including polymorphonuclear leukocytes, monocytes, macrophages, and fibroblasts. Penetration of the drug into phagocytic cells is necessary for activity against intracellular pathogens (e.g., *Staphylococcus aureus, Legionella pneumophila, Chlamydia trachomatis, Salmonella typhi*).

Spectrum
Azithromycin has an expanded spectrum of activity compared with erythromycin and clarithromycin. Azithromycin is active in vitro against many gram-positive and gram-negative aerobic and anaerobic bacteria as well as *Borrelia burgdorferi, Chlamydophila pneumoniae (Chlamydia pneumoniae), C. trachomatis, Mycoplasma pneumoniae, and Mycobacterium avium* complex (MAC). Azithromycin generally is more active in vitro against gram-negative organisms than erythromycin or clarithromycin and has activity comparable to erythromycin against most gram-positive organisms. Azithromycin has in vitro microbiologic activity similar to clarithromycin or erythromycin against *C. pneumoniae* and *M. pneumoniae*, but clarithromycin is fourfold more active against MAC in vitro than azithromycin. Streptococci and staphylococci that are resistant to erythromycin usually are resistant to azithromycin and clarithromycin. Azithromycin is not inactivated by β-lactamases produced by *H. influenzae* or *M. catarrhalis*. Azithromycin appears to have a postantibiotic inhibitory effect against susceptible gram-positive and gram-negative aerobic organisms. In in vitro studies, exposure of *S. pyogenes, S. pneumoniae,* or *H. influenzae* for 1–2 hours to azithromycin concentrations several times higher than the MIC for the organism resulted in a recovery period of about 3–4, 2.2–5, or 2.5–8 hours, respectively, after the drug was removed before the organism resumed growth.

Antimicrobial Action
Azithromycin is less active than erythromycin against streptococci and staphylococci, but has greater activity than erythromycin in vitro against some Gram-negative organisms