AZITHROMYCIN

AZEMAX

200 mg per 5 mL Powder for Suspension
500 mg Film-Coated Tablet

ANTIBACTERIAL (MACROLIDE)

FORMULATION
Each 5 mL (1 teaspoon) of reconstituted suspension contains:
Azithromycin (as monohydrate), USP ..... 200 mg
equivalent to Azithromycin

Each film-coated tablet contains:
Azithromycin (as monohydrate), USP ..... 500 mg
equivalent to Azithromycin

PRODUCT DESCRIPTION
Azithromycin (Azemax) is a nitrogen-containing macrolide or azalide with actions and uses similar to those of erythromycin. It is used in the treatment of a wide variety of infections caused by susceptible organisms.

Film-Coated Tablet: white to off-white, oblong, biconvex film-coated tablet, bisected on one side and plain on the other side.
Powder for Suspension: white to off-white free flowing powder and white to off-white suspension upon reconstitution.

PHARMACOKINETICS
Following oral administration about 40% of a dose of azithromycin is bioavailable. Absorption from the capsule, but not the tablet formulation is reduced by food. Peak plasma concentrations are achieved 2 to 3 hours after a dose, but azithromycin is extensively distributed to 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 Cerebrospinal fluid when the meninges are not inflamed. Small amounts of azithromycin are demethylated in the liver, and it is excreted in bile as unchanged drugs and metabolites. About 6% of an oral dose (representing about 20% of the amount in the synthetic circulation) is excreted in the urine. The terminal elimination half-life is probably in excess of 40 hours.

PHARMACODYNAMICS
Azithromycin has the same antimicrobial actions as erythromycin, only azithromycin is less active than erythromycin against streptococci and staphylococci, but has greater activity than erythromycin in vitro against some Gram-negative pathogens such as *Haemophilus influenzae* and *Moraxella catarrhalis (Branhamella catarrhalis)*, as well as having activity against some of the Enterobacteriaceae such as *Escherichia coli* and Salmonella and Shigella spp. Azithromycin is also more active than erythromycin against *Chlamydia trachomatis* and some opportunistic mycobacteria, including *Mycobacterium avium* complex. It has activity against protozoa *Toxoplasma gondii* and *Plasmodium falciparum*.

INDICATIONS
For the treatment of bronchitis, severe campylobacter enteritis, chancroid, diphtheria, Legionnaire's disease and other Legionella infections, neonatal conjunctivitis, pertussis, pneumonia, (mycoplasmal and other atypical pneumonia as well as streptococcal), sinusitis.

It is also used in situations where microorganisms sensitive to azithromycin have caused:
- Upper respiratory tract infections; sinusitis, pharyngitis, tonsilitis
- Acute otitis media
- Lower respiratory tract infections, acute bronchitis and mild to moderately severe community acquired pneumonia
- Skin and soft tissue infections
- Uncomplicated chlamydial urethritis & cervicitis

DOSAGE AND ADMINISTRATION
Film-coated Tablet:
Usual adult dose: 500 mg as single dose once daily for 3 days or alternatively, an initial dose of 500 mg may be followed by 250 mg daily for a further 4 days as prescribed by the physician.

Powder for Suspension:
Usual dose for children over 6 months of age for pneumonia or otitis media is 10 mg per kg on the first day , then 5 mg per kg daily for further 4 days, and the dose for pharyngitis in children aged over 2 years is 12 mg per kg daily for 5 days or as prescribed by the physician.

DIRECTION FOR RECONSTITUTION
200 mg per 5 mL Powder for Suspension:
To make 22.5 mL reconstituted suspension, add approximately 13 mL of water and shake well until the powder are evenly suspended. The reconstituted suspension is stable for five (5) days at temperatures not exceeding 30°C and two (2) weeks (14 days) under refrigerator (2-8°C).

WARNINGS AND PRECAUTIONS
Azithromycin should not be used in patients with hepatic impairment.
Prolonged cardiac repolarization and QT interval, imparting a risk of developing cardiac arrythmia and torsades de pointes, have been seen in patients treated with macrolides including azithromycin. Elderly patients may be more susceptible to drug-associated effects of QT interval.

The risk of QT prolongation which can be fatal should be considered when weighing the risk-benefit ratio of azithromycin when given to the following at-risk groups:
- Patients with known history of torsades de pointes or prolongation of QT interval
- Congenital long QT interval
- Bradyarrythmias or uncompensated heart failure
- Concomitant treatment with drugs known to prolong the QT interval
- Patients with existing proarrythmic conditions such as uncorrected hypokalemia or hypomagnesemia, clinically significant bradycardia and in patients receiving antiarrythmic agents such as quinidine, procainamide, dofetilide, amiodarone, sotalol.

CONTRAINDICATIONS
Azithromycin is contraindicated in patients with known hypersensitivity reactions to azithromycin, eruthromycin or any of the macrolide antibiotics.

DRUG INTERACTION
Antacid, Cimetidine, Zidovudine, Cyclosporin, Digoxin, Coumarin-type oral anticoagulants, Rifabulin, Nelfinavir, Carbamazepine, Phenytoin, Theophylline, Triazolam, Atorvastatin, Simvastatin, Alprazolam, Diazepam, Midazolam or Triazolam, Calcium Channel Blockers, Ergot medicine, other antibiotics such as Clarithromycin or Erythromycin.

ADVERSE EFFECTS
The most common adverse effect with azithromycin are gastrointestinal disturbances but are usually mild and less frequent than with erythromycin. Transient elevations of liver enzymes values have been reported and, rarely, cholestatic jaundice. Rashes, headache and dizziness may occur. Severe hypersensitive reactions occur rarely but may be prolonged. Transient alterations in neutrophil counts have been seen in patients receiving azithromycin.
There have been rare reports of QT prolongation and torsades de pointes (see Warning and Precautions).

OVERDOSE AND TREATMENT
For doses taken higher than the recommended dose, adverse events were similar to those seen at normal dose. In the event of an overdosage, general symptomatic and supportive measures are indicated as required.

STORAGE CONDITION
Store the tablet and powder for suspension at temperatures not exceeding 30°C.
Shake well the reconstituted suspension before use.

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

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph.
Seek advice from a healthcare professional at the first sign of any adverse drug reaction.

AVAILABILITY	REG. NO.	DATE OF 1st AUTHORIZATION
Azithromycin (Azemax) 500 mg Film-Coated Tablet 1 Alu-PVDC Blister pack x 3 tablets (Box of 3's)	DR-XY41106	15 February 2013
Azithromycin (Azemax) 200 mg per 5 mL Powder for Suspension 30 mL Plastic Bottle (white opaque) x 22.5 mL net content	DR-XY45321	22 April 2016

Marketing Authorization Holder:
THE CATHAY DRUG CO., INC.
2/F Vernida I Condominium, 120 Amorsolo St.
Legaspi Village, Makati City

Manufacturer:
LLOYD LABORATORIES, INC.
No. 10 Lloyd Ave., First Bulacan Industrial City
City of Malolos, Bulacan

Date of revision: May 2018