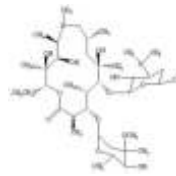


# Rx AZITHROMYCIN

(Azithromycin is a semi-synthetic macrolide antibiotic chemically related to erythromycin and clarithromycin (Biaxin))



**GENERIC NAME:** azithromycin

## DRUG CLASS AND MECHANISM

Azithromycin is a semi-synthetic macrolide antibiotic chemically related to erythromycin and clarithromycin (Biaxin). It is effective against a wide variety of bacteria such as *Hemophilus influenzae*, *Streptococcus pneumoniae*, *Mycoplasma pneumoniae*, *Staphylococcus aureus*, *Mycobacterium avium*, and many others. Azithromycin, like all macrolide antibiotics, prevents bacteria from growing by interfering with their ability to make proteins. Due to the differences in the way proteins are made in bacteria and humans, the macrolide antibiotics do not interfere with production of proteins in humans. It is an unusual antibiotic in that it stays in the body for quite a while (has a long half-life), allowing for once a day dosing and for shorter treatment courses for most infections. The FDA approved azithromycin in November 1991.

**PRESCRIPTION:** Yes

**GENERIC AVAILABLE:** Yes

## PREPARATIONS

Tablets: 250, 500, and 600 mg. Suspension: 100 mg/ teaspoon, 200 mg/teaspoon, 167 mg/teaspoon or 1 g/packet. Powder for Injection: 500 mg.

## PRESCRIBED FOR

Azithromycin is effective against susceptible bacteria causing otitis media (infection of the middle ear), tonsillitis, laryngitis, bronchitis, pneumonia, and sinusitis. It also is effective against several sexually transmitted infectious diseases such as nongonococcal urethritis and cervicitis.

## USES

Azithromycin is an antibiotic (macrolide-type) used to treat a wide variety of bacterial infections. This antibiotic only treats bacterial infections. It will not work for viral infections (e.g., common cold, flu). Unnecessary use or overuse of any antibiotic can lead to its decreased effectiveness.

## HOW TO USE

Take this medication by mouth with or without food, usually once a day, or as directed by your doctor. You may take this medication with food if stomach upset occurs. Antibiotics work best when the amount of medicine in your body is kept at a constant level. Therefore, take this drug at the same time each day. Continue to take this medication until the full prescribed amount is finished even if symptoms disappear after a few days. Stopping the medication too early may allow bacteria to continue to grow, which may result in a relapse of the infection. Antacids may decrease the absorption of azithromycin. If you take an antacid, wait at least 2 hours after taking this medication. Inform your doctor if your condition persists or worsens.

## SIDE EFFECTS

Stomach upset, diarrhea/loose stools, nausea, vomiting, or stomach/abdominal pain may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Tell your doctor immediately if any of these unlikely but serious side effects occur: hearing loss. Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: dark urine, persistent nausea/vomiting, severe stomach/abdominal pain, yellowing of the eyes or skin. This medication may rarely cause a severe intestinal condition (pseudomembranous colitis) due to a resistant bacteria. This condition may occur weeks after treatment has stopped. Do not use anti-diarrhea products or narcotic pain medications if you have the following symptoms because these products may make them worse. Tell your doctor immediately if you develop: persistent diarrhea, abdominal or stomach pain/cramping, or blood/mucus in your stool. Use of this medication for prolonged or repeated periods may result in oral thrush or a new vaginal yeast infection (oral or vaginal fungal infection). Contact your doctor if you notice white patches in your mouth, a change in vaginal discharge or other new symptoms. A serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction include: rash, itching, swelling, dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

## DRUG INTERACTIONS

See also the How to Use section. Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: aluminum- and magnesium-containing antacids, digoxin, live vaccines, lovastatin, nelfinavir, warfarin. This medication may decrease the effectiveness of combination-type birth control pills. This can result in pregnancy. You may need to use an additional form of reliable birth control while using this medication. Consult your doctor or pharmacist for details. Other drugs besides azithromycin which may affect the heart rhythm (QTc prolongation in the EKG) include dofetilide, pimozide, procainamide, quinidine, sotalol, and sparfloxacin among others. QTc prolongation can infrequently result in serious, rarely fatal, irregular heartbeats. Consult your doctor or pharmacist for details. Ask for instructions about whether you need to stop any other QTc-prolonging drugs you may be using in order to minimize the risk of this effect. Do not start or stop any medicine without doctor or pharmacist approval.

## OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. Symptoms of overdose may include: severe or persistent diarrhea.

## DOSING

Azithromycin (except Zmax) can be taken with or without food, but food reduces stomach upset. Zmax should be taken on an empty stomach 1 hour before or 2 hours after a meal since food reduces its absorption. The adult azithromycin dose is 500-2000 mg in multiple or single doses. For most infections, azithromycin is taken once daily for a relatively short course of treatment (usually five days). The first dose is often a "double dose," twice as much as the remainder of the doses given. For acute bacterial sinusitis, azithromycin may be taken once daily for three days. Zmax usually is given as a single 2 gm dose.

## PRECAUTIONS

Before taking azithromycin, tell your doctor or pharmacist if you are allergic to it; or to other macrolide antibiotics such as erythromycin, clarithromycin; or if you have any other allergies. Before using this medication, tell your doctor or pharmacist your medical history, especially of: liver disease, kidney disease. This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. This drug passes into breast milk. Consult your doctor before breast-feeding.

## MISSED DOSE

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

## STORAGE

Store at room temperature between 59-86 degrees F (15-30 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.

**Note :** This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around

\*\*\*  
**Taj DRUG** WORLD

Taj Group of Companies <sup>INDIA</sup>

Taj Pharmaceuticals Ltd.

Phone : General EPA BX : 91 - (0)22 - 26374592/92 91,  
(0)22 - 26374592/93 91 - (0)22 - 30601000,  
Fax : 91-(0)22-26341274

Revised November 2010