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Patient Information

Azithromycin (ay-ZITH-roe-MYE-sin) Tablets USP

Read this Patient Information leaflet before you start taking azithromycin tablets and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What are azithromycin tablets?

Azithromycin tablets are a macrolide antibiotic prescription medicine used in adults 18 years or older to treat certain infections caused by certain germs called bacteria. These bacterial infections include:

- acute worsening of chronic bronchitis
- acute sinus infection
- community-acquired pneumonia
- infected throat or tonsils
- skin infections
- infections of the urethra or cervix
- genital ulcers in men

Azithromycin tablets are also used in children to treat:

- ear infections
- community-acquired pneumonia
- infected throat or tonsils

Azithromycin should not be taken by people who cannot tolerate oral medications because they are very ill or have certain other risk factors including:

- have cystic fibrosis
- have hospital acquired infections
- have known or suspected bacteria in the blood
- need to be in the hospital
- are elderly
- have any medical problems that can lower the ability of the immune system to fight infections

Azithromycin tablets are not for viral infections such as the common cold.

It is not known if azithromycin tablets are safe and effective for genital ulcers in women.

It is not known if azithromycin tablets are safe and effective for children with ear infections, sinus infections, and community-acquired pneumonia under 6 months of age.

It is not known if azithromycin tablets are safe and effective for infected throat or tonsils in children under 2 years of age.

Who should not take azithromycin tablets?

Do not take azithromycin tablets if you:

- have had a severe allergic reaction to certain antibiotics known as macrolides or ketolides including azithromycin and erythromycin.
- have a history of cholestatic jaundice or hepatic dysfunction that happened with the use of azithromycin.

What should I tell my healthcare provider before taking azithromycin tablets?

Before you take azithromycin tablets, tell your healthcare provider if you:

- have pneumonia
- have cystic fibrosis
- have known or suspected bacteremia (bacterial infection in the blood)
- have liver or kidney problems
- have an irregular heartbeat, especially a problem called “QT prolongation”
- have a problem that causes muscle weakness (myasthenia gravis)
- have any other medical problems
- are pregnant or plan to become pregnant. It is not known if azithromycin tablets will harm your unborn baby.
- are breastfeeding or plan to breastfeed. Azithromycin has been reported to pass into breast milk. Talk to your healthcare provider about the best way to feed your baby while you take azithromycin tablets.

Contact your healthcare provider immediately if you are giving azithromycin tablets to a young child (less than 6 weeks of age) and he or she vomits or becomes irritable when fed.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Azithromycin tablets and other medicines may affect each other causing side effects. Azithromycin tablets may affect the way other medicines work, and other medicines may affect how azithromycin tablets works.

Especially tell your healthcare provider if you take:

- nelfinavir
- a blood thinner (warfarin)
- digoxin
- colchicine
- phenytoin
- an antacid that contains aluminum or magnesium

Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take azithromycin tablets?

- Take azithromycin tablets exactly as your healthcare provider tells you to take it.
- Azithromycin tablets can be taken with or without food.
- Do not skip any doses of azithromycin tablets or stop taking it, even if you begin to feel better, until you finish your prescribed treatment unless you have a serious allergic reaction or your healthcare provider tells you to stop taking azithromycin tablets. **“See What are the possible side effects of azithromycin tablets?”** If you skip doses, or do not complete the total course of azithromycin tablets your treatment may not work as well and your infection may be harder to treat. Taking all of your azithromycin tablets doses will help lower the chance that the bacteria will become resistant to azithromycin tablets.
- If the bacteria becomes resistant to azithromycin, azithromycin tablets and other antibiotic medicines may not work for you in the future.
- If you take too much azithromycin tablets, call your healthcare provider or get medical help right away.

What are the possible side effects of azithromycin tablets?

Azithromycin tablets can cause serious side effects, including:

- **Serious allergic reactions.** Allergic reactions can happen in people taking azithromycin tablets the active ingredient in azithromycin tablets, even after only 1 dose. Stop taking azithromycin tablets and get emergency medical help right away if you have any of the following symptoms of a severe allergic reaction:
 - trouble breathing or swallowing
 - swelling of the lips, tongue, face
 - throat tightness, hoarseness
 - rapid heartbeat
 - faintness
 - skin rash (hives)
 - new onset of fever and swollen lymph nodes

Stop taking azithromycin tablets at the first sign of a skin rash and call your healthcare provider.

Skin rash may be a sign of a more serious reaction to azithromycin tablets.

- **Liver damage (hepatotoxicity).** Hepatotoxicity can happen in people who take azithromycin tablets. Call your healthcare provider right away if you have unexplained symptoms such as:
 - nausea or vomiting
 - stomach pain
 - fever
 - weakness
 - abdominal pain or tenderness
 - itching
 - unusual tiredness
 - loss of appetite
 - change in the color of your bowel movements
 - dark colored urine
 - yellowing of your skin or of the whites of your eye

Stop taking azithromycin tablets and tell your healthcare provider right away if you have

yellowing of your skin or white part of your eyes, or if you have dark urine. These can be signs of a serious reaction to azithromycin tablets (a liver problem).

- **Serious heart rhythm changes that can be life-threatening, including heart stopping (cardiac arrest), QT prolongation, torsades de pointes, feeling that your heart is pounding or racing (palpitations), chest discomfort, or irregular heartbeat.**
Tell your healthcare provider right away if you or your child feel a fast or irregular heartbeat, get dizzy or faint. Azithromycin tablets may cause a rare heart problem known as prolongation of the QT interval. This condition can cause an abnormal heartbeat and can be very dangerous. The chances of this happening are higher in people:
 - who are elderly
 - with a family history of prolonged QT interval
 - with low blood potassium
 - who take certain medicines to control heart rhythm (antiarrhythmics)
- **Worsening of myasthenia gravis (a problem that causes muscle weakness).**
Certain antibiotics like azithromycin tablets may cause worsening of myasthenia gravis symptoms, including muscle weakness and breathing problems. Call your healthcare provider right away if you have any worsening muscle weakness or breathing problems.
- **Diarrhea.** Tell your healthcare provider right away if you have watery diarrhea, diarrhea that does not go away, or bloody stools. You may experience cramping and a fever. This could happen after you have finished your azithromycin tablets.
The most common side effects of azithromycin tablets include:
 - nausea
 - stomach pain
 - vomiting

These are not all the possible side effects of azithromycin tablets. Tell your healthcare provider about any side effect that bothers you or that does not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store azithromycin tablets?

- Store azithromycin tablets at 15° to 30°C (59° to 86°F).
- Safely throw away any medicine that is out of date or no longer needed.

Keep azithromycin tablets and all medicines out of the reach of children.

General information about the safe and effective use of azithromycin tablets.

Medicines are sometimes prescribed for purposes other than those listed in the Patient Information leaflet. Do not use azithromycin tablets for a condition for which it was not prescribed. Do not give azithromycin tablets to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes the most important information about azithromycin tablets. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about azithromycin tablets that is written for health professionals.

For more information, go to www.lupinpharmaceuticals.com or call 1-800-399-2561

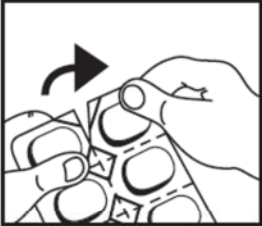
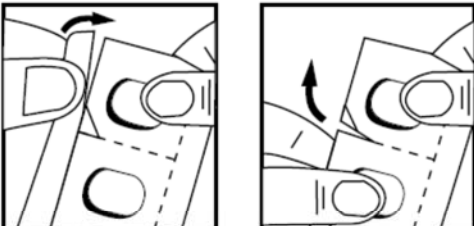
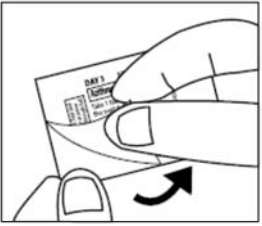
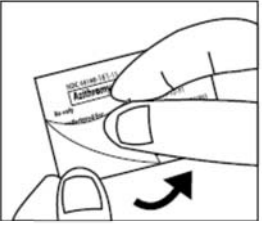
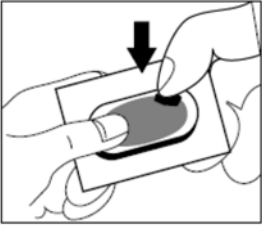
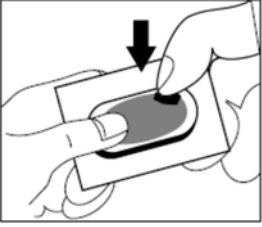
What are the ingredients in azithromycin tablets?

Azithromycin Tablets:

Active ingredient: azithromycin monohydrate

Inactive ingredients: croscarmellose sodium, dibasic calcium phosphate, hydroxypropyl methyl cellulose, lactose monohydrate, magnesium stearate, sodium lauryl sulfate, titanium dioxide, triacetin and D & C Red #30.

How to open the blister:

Azithromycin tablets, 250 mg	Azithromycin tablets, 500 mg
<p>1. Tear along the perforation to separate</p> 	<p>1. Tear along the perforation to separate</p> 
<p>2. Peel the paper from arrow to expose foil</p> 	<p>2. Peel the paper from arrow to expose foil</p> 
<p>3. Push tablet through foil</p> 	<p>3. Push tablet through foil</p> 

This Patient Information has been approved by the U.S. Food and Drug Administration.

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