

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION**

**Pr APO-AZITHROMYCIN Z
Azithromycin Tablets USP**

Read this carefully before you start taking **AP0-AZITHROMYCIN Z** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **AP0-AZITHROMYCIN Z**.

What is APO-AZITHROMYCIN Z used for?

AP0-AZITHROMYCIN Z is an antibiotic medicine used to treat the following types of **mild to moderate** infections **by certain microorganisms** in adults such as bronchitis, certain types of skin infections, strep throat (pharyngitis, tonsillitis), genitourinary infections, and pneumonia.

Antibacterial drugs like **AP0-AZITHROMYCIN Z** treat only bacterial infections. They do not treat viral infections such as the common cold. Although you may feel better early in treatment, **AP0-AZITHROMYCIN Z** should be taken exactly as directed. Misuse or overuse of **AP0-AZITHROMYCIN Z** could lead to the growth of bacteria that will not be killed by **AP0-AZITHROMYCIN Z** (resistance). This means that **AP0-AZITHROMYCIN Z** may not work for you in the future. Do not share your medicine.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of **AP0-AZITHROMYCIN Z** and other antibacterial drugs, **AP0-AZITHROMYCIN Z** should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

How does APO-AZITHROMYCIN Z work?

AP0-AZITHROMYCIN Z helps stop the growth of the bacteria that cause infection. It gets into infected tissue where it is released slowly over time so the medicine keeps fighting bacteria for many days after the last dose is taken. This is why **AP0-AZITHROMYCIN Z** may be taken for as short a time as one day.

What are the ingredients in APO-AZITHROMYCIN Z?

Medicinal ingredients: Azithromycin dihydrate

Non-medicinal ingredients: croscarmellose sodium, dibasic calcium phosphate dihydrate, hydroxypropyl cellulose, HPMC 2910/hypromellose, lactose monohydrate, magnesium stearate, titanium dioxide, and triacetin.

AP0-AZITHROMYCIN Z comes in the following dosage forms:

Tablets: 250 mg

Do not use APO-AZITHROMYCIN Z if you:

- have a history of liver problems when you have used azithromycin.
- are hypersensitive (allergic) to azithromycin, or any macrolide or ketolide antibiotic (including erythromycin) or any other ingredient of **AP0-AZITHROMYCIN Z** (see **What are the ingredients in APO-AZITHROMYCIN Z?**).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take APO-AZITHROMYCIN Z. Talk about any health conditions or problems you may have, including if you:

- have a known prolonged heart cycle (interval) (QT prolongation)

- are currently taking medication known to prolong QT interval (prolong your heart cycle) such as antiarrhythmics (drugs to regulate your heart beat such as class IA: quinidine, procainamide and class III; dofetilide, amiodarone, sotalol); antipsychotic agents; antidepressants; and fluoroquinolones (a class of antibiotics)
- have a history of life-threatening irregular heart beat
- have constantly low levels of potassium or magnesium in your blood
- have a history for heart problems such as slow heart rate, irregular heart beat or cardiac insufficiency (your heart has a hard time pumping blood to your body)
- are pregnant or think you are pregnant,
- are breastfeeding or planning to breastfeed. Azithromycin has been reported to be excreted in human breast milk. It is not known if **APO-AZITHROMYCIN Z** could affect your baby. Discuss with your doctor.
- have ever had any liver or kidney problems
- have a weak immune system
- have ever had an allergic reaction to any medicines, including antibiotics such as erythromycin
- have myasthenia gravis (a chronic autoimmune neuromuscular disease which causes muscle weakness)
- have hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption as this product contains lactose.

Other warnings you should know about:

You should begin to feel better within the first few days, but be sure to take **APO-AZITHROMYCIN Z** for the full number of days your doctor prescribed. Although **APO-AZITHROMYCIN Z**'s dosing is short, you should not expect **APO-AZITHROMYCIN Z** to work faster than other antibiotics which are dosed up to 10 days. If you stop taking **APO-AZITHROMYCIN Z** too soon, your infection could come back. The next infection may be worse and be more difficult to treat. If you are not able to take all the medicine, tell your doctor.

If you develop diarrhea during or after treatment with **APO-AZITHROMYCIN Z**, tell your doctor at once. Do not use any medicine to treat your diarrhea without first checking with your doctor.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with APO-AZITHROMYCIN Z:

- Warfarin (or other anticoagulant medicine);
- Cyclosporin (used to suppress the immune system to prevent and treat rejection in organ or bone marrow transplants);
- Digoxin (used for treatment of heart problem);
- Nelfinavir (used for treatment of HIV infections);
- Ergotamine and ergot derivatives (used for migraine treatment). Ergotamine and ergot derivatives should not be used with **APO-AZITHROMYCIN Z**.

Some medicines may affect how well **APO-AZITHROMYCIN Z** works. Check with your doctor before starting any new prescription or over-the-counter medicines, including natural/herbal remedies or antacids, while on **APO-AZITHROMYCIN Z**.

How to take APO-AZITHROMYCIN Z:

Always take **APO-AZITHROMYCIN Z** as the doctor has prescribed for you, depending on the specific condition you have.

APO-AZITHROMYCIN Z can be taken with or without food.

Usual adult dose:

If your doctor prescribes **APO-AZITHROMYCIN Z 250 mg tablets** for 3 days for treatment of bronchitis:

Days 1 through 3: Take two tablets each day.

If your doctor prescribes the 5 day **APO-AZITHROMYCIN Z 250 mg tablets** for 5 days for treatment of respiratory tract infections or certain types of skin infections:

Day 1: Take 2 tablets once.

Day 2 through 5: Take 1 tablet daily.

If your doctor prescribes **APO-AZITHROMYCIN Z 250 mg tablets** for 1 day for treatment of genital ulcers or non-gonococcal urethritis and cervicitis:

Days 1: Take four tablets once.

If your doctor prescribes **APO-AZITHROMYCIN Z 250 mg tablets** for 1 day for treatment of gonococcal urethritis and cervicitis:

Days 1: Take eight tablets once.

Overdose:

If you think you have taken too much **APO-AZITHROMYCIN Z**, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take a dose, call your pharmacist or doctor. Do not double dose.

What are possible side effects from using APO-AZITHROMYCIN Z?

These are not all the possible side effects you may feel when taking **APO-AZITHROMYCIN Z**. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Diarrhea/loose stools
- Stomach pain
- Nausea and vomiting
- Headache

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON Clostridium difficile colitis (bowel inflammation): severe diarrhea (bloody or watery) with or without fever, abdominal pain, or tenderness			√
UNCOMMON Abnormal heart rhythm: feel your heart beating in your chest, abnormal heartbeat, dizziness or feeling faint			√

Severe allergic reaction: trouble breathing, swelling of the face, mouth, throat, neck, severe skin rash or blisters			√
Liver disorder: abdominal pain, nausea, vomiting, yellowing of skin and eyes, dark urine			√
Myasthenia gravis: muscle weakness, drooping eyelid, vision changes, difficulty chewing and swallowing, trouble breathing		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store **APO-AZITHROMYCIN Z** at controlled room temperature (between 15°C to 30°C).

Keep out of reach and sight of children.

If you want more information about APO-AZITHROMYCIN Z:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](http://www.healthcanada.gc.ca) (www.healthcanada.gc.ca); the manufacturer's website <http://www.apotex.ca/products>, or by calling 1-800-667-4708.

This leaflet was prepared by Apotex Inc., Toronto, Ontario, M9L 1T9.

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