

PART III: CONSUMER INFORMATION

Pr APO-AZITHROMYCIN

Azithromycin Isopropanolate Monohydrate
250 mg tablets

This leaflet is part III of a three-part “Product Monograph” published when APO-AZITHROMYCIN was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about APO-AZITHROMYCIN. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

APO-AZITHROMYCIN is an antibiotic medicine 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, disseminated mycobacterium avium complex (MAC) disease in people with HIV, and pneumonia.

This medication is indicated for adult patients. Your doctor will decide on whether **APO-AZITHROMYCIN** is most appropriate antibacterial for you.

What it does:

APO-AZITHROMYCIN helps stop the growth of the bacteria that cause infection. It gets into infected tissue where it is released slowly over time. The medicine fights the infection for several days after the last dose is taken.

Antibiotics work only on infections caused by bacteria. They do not kill viruses. No antibiotics, including **APO-AZITHROMYCIN**, can treat viral infections such as the common cold and the flu.

When it should not be used:

- If you have a history of cholestatic jaundice/hepatitis (liver problems) associated with prior use of azithromycin.
- If you are hypersensitive (allergic) to azithromycin, or any macrolide or ketolide antibiotic (including

erythromycin) or any other ingredient of **APO-AZITHROMYCIN** (see What the nonmedicinal ingredients are),

What the medicinal ingredient is:

Azithromycin Isopropanolate monohydrate

What the non-medicinal ingredients are:

APO-AZITHROMYCIN Tablets 250 mg contain microcrystalline cellulose, stearic acid, croscarmellose sodium, magnesium stearate, colloidal silicon dioxide, hydroxyethyl cellulose, polyethylene glycol, titanium dioxide, D&C red #30 and vitamin E.

What dosage forms it comes in:

Tablets

WARNINGS AND PRECAUTIONS

BEFORE you use APO-AZITHROMYCIN talk to your doctor or pharmacist if you:

- are taking prescription medicines or any over the counter medicines you can buy without a prescription, including natural/herbal remedies or antacids (See **Interactions With This Medication**)
- you have a known prolonged heart cycle (interval) (QT prolongation)
- you are currently taking medication known to prolong QT intervals (prolong your heart cycle) such as antiarrhythmics (drugs to regulate your heart such as class IA: quinidine, procainamide and class III; dofetilide, amiodarone, sotalol); antipsychotic agents; antidepressants; and fluoroquinolones (a class of antibiotics)
- you have a history of life-threatening irregular heart beat
- you have constantly low levels of potassium or magnesium
- you have a history for heart problems such as bradycardia (slow heart rate), cardiac arrhythmia (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 breast-feeding. Azithromycin has been reported to be excreted in human breast milk. It is not known if **APO-AZITHROMYCIN** 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 ever had an allergic reaction to azithromycin or any of the ingredients of **APO-AZITHROMYCIN** tablets
- Have myasthenia gravis (a chronic autoimmune neuromuscular disease which causes muscle weakness)

You should begin to feel better within the first few days, but be sure to take **APO-AZITHROMYCIN** for the full number of days your doctor prescribed. Although **APO-AZITHROMYCIN**'s dosing is short, you should not expect **APO-AZITHROMYCIN** to work faster than other antibiotics which are dosed up to 10 days. If you stop taking **APO-AZITHROMYCIN** too soon, your infection could come back. The next infection may be worse and 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, tell your doctor at once. Do not use any medicine to treat your diarrhea without first checking with your doctor.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with **APO-AZITHROMYCIN** include:

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

Some medicines may affect how well **APO-AZITHROMYCIN** 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**.

PROPER USE OF THIS MEDICATION

Usual adult dose:

APO-AZITHROMYCIN can be taken with or without food.

If your doctor prescribes **APO-AZITHROMYCIN** for 3 days for treatment of bronchitis:

Days 1 through 3: Take two tablets each day.

If your doctor prescribes the 5 days **APO-AZITHROMYCIN** pack 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.

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

Overdose

In case of drug overdose, contact a healthcare professional, hospital emergency department or regional poison control centre, even if there are no symptoms.

Missed Dose

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

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with most drugs, **APO-AZITHROMYCIN** can cause some side effects.

The most common side effects are diarrhea/loose stools, stomach pain, nausea, and vomiting.

If you experience symptoms such as severe diarrhea (bloody or watery) with or without fever, abdominal pain, or tenderness, you may have Clostridium difficile colitis (bowel inflammation). If this occurs, stop taking **APO-**

AZITHROMYCIN and contact your healthcare professional immediately.

Allergic reactions to **APO-AZITHROMYCIN** are rare, but these reactions can be very serious if not treated right away by a doctor. If you think you might be having an allergic reaction to **APO-AZITHROMYCIN**, call your doctor right away. If you cannot reach your doctor, go to the nearest hospital emergency room. Symptoms of a severe allergic reaction may include trouble breathing; swelling of the face, mouth and neck; or severe skin rash or blisters.

If you develop symptoms of hepatitis (liver inflammation) such as abdominal pain, nausea, vomiting, yellowing of skin and eyes, dark urine etc., stop taking the medicine immediately and call the doctor or nurse.

If you develop symptoms of myasthenia gravis or the symptoms of your existing myasthenia gravis worsen, contact your doctor. These symptoms could include muscle weakness that gets worse with activity and gets better with rest, drooping eyelid, blurred or double vision, difficulty chewing and swallowing, or trouble breathing.

Please tell your doctor right away if you feel your heart beating in your chest or if you have an abnormal heartbeat or get dizzy or faint when taking **APO-AZITHROMYCIN**.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call medical attention
		Only if severe	In all cases	
Common	Diarrhea/loose stools	✓		
	Nausea	✓		
	Stomach pain	✓		
	Headache	✓		
	Vomiting	✓		
Uncommon	Abnormal heart rhythm			✓
	Allergic reaction (ie. trouble breathing, swelling of the face, mouth, and neck skin rash)			✓
	Liver disorder (symptoms include abdominal pain, nausea, vomiting, yellowing of skin and eyes, dark urine)			✓
Uncommon	Myasthenia gravis (muscle weakness, drooping eyelid, vision changes, difficulty chewing and swallowing, trouble breathing)		✓	

*This is not a complete list of side effects. For any unexpected effects while taking **APO-AZITHROMYCIN**, contact your doctor or pharmacist.*

HOW TO STORE IT

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

Keep **APO-AZITHROMYCIN** and all medicines out of the reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator: 0701E
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at

www.healthcanada.gc.ca/medeffect.

Note: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For more information, please contact your doctor, pharmacist or other healthcare professional.

This leaflet plus the full product monograph, prepared for health professionals, can be obtained by contacting DISpedia, Apotex's Drug Information Service at:
1-800-667-4708

This leaflet can also be found at:

<http://www.apotex.ca/products>.

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