

CONSUMER INFORMATION

Pr **PRO-AZITHROMYCINE**
Azithromycin Tablets, USP

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

ABOUT THIS MEDICATION**What the medication is used for:**

PRO-AZITHROMYCINE 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 PRO-AZITHROMYCINE is the most appropriate antibacterial for you.

What it does:

PRO-AZITHROMYCINE 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 antibiotic, including PRO-AZITHROMYCINE, 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 PRO-AZITHROMYCINE (see **What the nonmedicinal ingredients are**).

What the medicinal ingredient is:

Azithromycin, as azithromycin dihydrate.

What the important nonmedicinal ingredients are:

croscarmellose sodium, hydroxypropylmethyl cellulose, lactose, magnesium stearate, poloxamer 188, povidone, silicified microcrystalline cellulose, polyethylene glycol, talc and titanium dioxide.

250 mg tablets also contain D&C Red No. 27, FD&C Blue No. 2, FD&C Red No. 40, FD&C Yellow No.6.

600 mg tablets also contain hydroxypropyl cellulose.

What dosage forms it comes in:

Tablets: 250 mg and 600 mg.

WARNINGS AND PRECAUTIONS

BEFORE you use PRO-AZITHROMYCINE talk to your doctor or pharmacist if you :

- are taking any 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)
- 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 PRO-AZITHROMYCINE 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 PRO-AZITHROMYCINE tablets
- have myasthenia gravis (a chronic autoimmune neuromuscular disease which causes muscle weakness)
- have a rare hereditary problem of fructose intolerance, glucose/galactose malabsorption or sucrase isomaltase insufficiency, as this product contains lactose.

You should begin to feel better within the first few days, but be sure to take PRO-AZITHROMYCINE for the full number of days your doctor prescribed. Although PRO-AZITHROMYCINE dosing is short, you should not expect PRO-AZITHROMYCINE to work faster than other antibiotics which are dosed up to 10 days. If you stop taking PRO-AZITHROMYCINE 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, 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 PRO-AZITHROMYCINE 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 treatment of HIV infections);
- Ergotamine and ergot derivatives (used for migraine treatment). Ergotamine and ergot derivatives should not be used with PRO-AZITHROMYCINE.

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

PROPER USE OF THIS MEDICATION

Usual adult dose:

PRO-AZITHROMYCINE can be taken with or without food.

If your doctor prescribes the 3 day PRO-AZITHROMYCINE 250 mg tablets for treatment of bronchitis:

Days 1 through 3: Take 1 tablet each day.

If your doctor prescribes PRO-AZITHROMYCINE 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 PRO-AZITHROMYCINE 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.

Always take PRO-AZITHROMYCINE as the doctor has prescribed for you, depending on the specific condition you have.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Center immediately, even if there are no symptoms.

Missed Dose:

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

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with most drugs, PRO-AZITHROMYCINE can cause some side effects.

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

As with other antibacterials, if you develops diarrhea that becomes severe and watery or does not go away, call your doctor. This could be a sign of a serious medical problem.

Allergic reactions to PRO-AZITHROMYCINE 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 PRO-AZITHROMYCINE, 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 your 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 **PRO-AZITHROMYCINE**.

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 seek immediate emergency medical attention
		Only if severe	In all cases	
Common	Diarrhea/loose stools	<input type="checkbox"/>		
	Nausea	<input type="checkbox"/>		
	Stomach pain	<input type="checkbox"/>		
	Headache	<input type="checkbox"/>		
	Vomiting	<input type="checkbox"/>		
Uncommon	Abnormal heart rhythm			<input type="checkbox"/>
	Allergic reaction (ie. trouble breathing, swelling of the face, mouth, and neck skin rash)			<input type="checkbox"/>
	Liver disorder (symptoms include abdominal pain, nausea, vomiting, yellowing of skin and eyes, dark urine)			<input type="checkbox"/>
	Myasthenia gravis (muscle weakness, drooping eyelid, vision changes, difficulty chewing and swallowing, trouble breathing)		<input type="checkbox"/>	

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

HOW TO STORE IT

Store between 15°C and 30°C

Keep PRO-AZITHROMYCINE 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

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, <http://www.prodoc.qc.ca> or info@prodoc.qc.ca.

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