

PART III: CONSUMER INFORMATION

Pr BIAXIN® XL

clarithromycin extended-release tablets, Abbott Standard

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

ABOUT THIS MEDICATION

What the medication is used for:

BIAXIN® XL is used to treat certain infections caused by bacteria, such as pneumonia, bronchitis and infections of the sinuses.

The efficacy and safety of BIAXIN® XL in treating other infections for which BIAXIN BID® and BIAXIN® are approved have not been established.

What it does:

BIAXIN® XL is an antibiotic that kills bacteria in your body.

When it should not be used:

Do not take BIAXIN® XL if you have ever had an allergic reaction to it, or if you are sensitive to it or erythromycin, or other antibacterial agents of the same family or to any ingredient in the formulation. See (**What the important non-medicinal ingredients are**).

Do not take BIAXIN® XL if you are taking astemizole*, cisapride*, colchicine, pimozone, terfenadine*, ergotamine, dihydroergotamine, lovastatin or simvastatin. Astemizole*, cisapride*, pimozone, terfenadine*, ergotamine, dihydroergotamine and colchicine can interact with BIAXIN® XL, possibly leading to an irregular heartbeat pattern; deaths have occurred.

* no longer marketed in Canada.

Do not take BIAXIN® XL if you have ever developed liver problems after using BIAXIN® XL.

Do not use BIAXIN® XL if you have a history of heart disturbance or irregular heart beat (arrhythmias, QT prolongation, torsade de points).

What the medicinal ingredient is:

The medicinal ingredient is clarithromycin.

What the important non-medicinal ingredients are:

The non-medicinal ingredients are the following: cellulosic polymers, lactose monohydrate, magnesium stearate, propylene

glycol, Quinoline Yellow Lake E104, sorbitan monooleate, talc, titanium dioxide and vanillin.

What dosage forms it comes in:

This medicine comes in:

- extended-release tablets (BIAXIN® XL, 500 mg),
- regular tablets (BIAXIN BID®, 250 mg and 500 mg),
- liquid forms (BIAXIN®, 125 mg/5mL and 250 mg/5mL).

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

BIAXIN® XL should not be used in pregnancy unless advised by your doctor due to potential hazards to the fetus. Do not take BIAXIN® XL without first talking to your doctor if you are breast-feeding a baby.

Before taking BIAXIN® XL, tell your doctor if you have liver or kidney disease. You may not be able to take clarithromycin, or you may require a lower dose and special monitoring during therapy. Talk to your doctor if BIAXIN® XL gives you prolonged and severe diarrhea.

The development of antibiotic resistance has been seen in patients with HIV receiving clarithromycin. To avoid failure of the treatment with a potential for developing antimicrobial resistance and a risk of failure with subsequent therapy, you/your child should follow closely the prescribed regimen.

BEFORE you use BIAXIN® XL talk to your doctor or pharmacist:

- about all health problems you have now or have had in the past;
- about all other medicines you are taking, including non-prescription medicines, nutritional supplements, or herbal products. See (**INTERACTIONS WITH THIS MEDICATION**);
- if you have or develop severe diarrhea as this may be a sign of a more serious condition;
- if you have kidney problems;
- if you have liver problems;
- if you are taking astemizole, terfenadine, cisapride, pimozone, ergotamine, dihydroergotamine, digoxin, colchicine, lovastatin or simvastatin.
- if you have any unusual or allergic reaction (rash, difficulty breathing) to clarithromycin or any of the non-medicinal ingredients in BIAXIN® XL (see **What the important non-medicinal ingredients are**), other medicines, foods, dyes, or preservatives;
- if you are pregnant, trying to get pregnant or are breast-feeding because clarithromycin has been detected in human breast milk.

- if you are elderly with a history of liver or kidney problems and taking colchicine.

WHILE taking BIAXIN® XL, contact your doctor if:

- You develop symptoms of myasthenia gravis or the symptoms of your existing myasthenia gravis worsen. 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.
- You develop symptoms of hepatitis (liver inflammation) such as abdominal pain, nausea, vomiting, yellowing of skin and eyes, dark urine etc. Stop taking the drug immediately.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with BIAXIN® XL includes:

Alfentanil, alprazolam, amlodipine, astemizole*/terfenadine*, atazanavir, atorvastatin, bromocriptine, carbamazepine, cilostazol, cisapride*/pimozide, colchicine, cyclosporine, digoxin, diltiazem, disopyramide/quinidine, efavirenz, ergotamine/dihydroergotamine, etravirine, fluconazole, hexobarbital, insulin, itraconazole, lansoprazole/omeprazole, lovastatin/simvastatin, methylprednisolone, midazolam/triazolam, nateglinide, nevirapine, phenobarbital, phenytoin, pioglitazone, repaglinide, rifabutin/rifampin, rifapentine*, ritonavir/indinavir, rosiglitazone, rosuvastatin, saquinavir, sildenafil, St. John’s Wort (*Hypericum perforatum*), tacrolimus, tadalafil, theophylline, tolterodine, valproic acid, vardenafil, verapamil, vinblastine, warfarin/acenocoumarol, zidovudine and drugs metabolized by cytochrome P450 system.

*not marketed in Canada.

PROPER USE OF THIS MEDICATION

Usual Dose:

BIAXIN® XL must be taken with food.

Adults with Respiratory Tract Infection:

The usual adult dosage is 1000 mg every 24 hours for 5 to 14 days.

BIAXIN® XL should be swallowed whole, with a glass of water and not chewed, broken or crushed.

Overdose:

In case of overdose, contact your healthcare professional, hospital emergency department or regional poison control centre, even if there are no symptoms. Symptoms of BIAXIN® XL overdose are abdominal pain, vomiting, nausea, and diarrhea.

Missed Dose:

If you miss a dose, take it as soon as you remember unless it is almost time for the next dose. In that case, skip the missed dose and take the next one as directed. Do not take double or extra doses.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, BIAXIN® XL can cause side effects. The majority of side effects observed in clinical trials with BIAXIN® XL were of a mild and transient nature.

The following adverse reactions were reported during the clinical studies with clarithromycin, the medicinal ingredient (occurring between 1% and 10% in clinical trials) or during post-marketing surveillance: abdominal pain, abnormal taste, diarrhea, ear disorder, flatulence, indigestion, headache, nausea, rash, vomiting. Talk to your doctor or pharmacist if any of these side effects persist or become bothersome.

If you see tablet residue in your stool, contact your doctor as your doctor may recommend a different clarithromycin formulation, especially if you have certain bowel conditions.

Serious side effects from BIAXIN® XL are not common.

If dizziness, confusion or disorientation occur while taking BIAXIN® XL, do not drive or operate machinery.

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 your doctor or pharmacist
		Only if severe	In all cases	
Uncommon	Allergic reactions*			✓
	Severe diarrhea		✓	
	Severe abdominal cramps		✓	
	Irregular heart beat			✓

*Allergic reactions, with symptoms such as itching, skin eruptions, rash, sore throat, fever, swelling, skin rash, itchiness, difficulty breathing, lightheadedness/dizziness.

This is not a complete list of side effects. For any unexpected effects while taking BIAXIN® XL, contact your doctor or pharmacist.

HOW TO STORE IT

Keep BIAXIN[®] XL and all other medicines out of reach of children.

Store at room temperature (15 to 25°C) in a tightly closed container. Protect from light. Do not use beyond the expiration date.

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 on line 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**
 - **Mail to: Canada Vigilance Program**
Health Canada
Postal Locator 0701D
Ottawa, ON K1A 0K9

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

<http://www.abbott.ca>

or by contacting the sponsor, Abbott Laboratories, Limited, Saint-Laurent, Qc H4S 1Z1 at:
1-800-699-9948

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