

PART III: PATIENT MEDICATION INFORMATION
READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrBIAXIN® XL
clarithromycin extended-release tablets
Manufacturer's Standard

Read this carefully before you start taking **BIAXIN® XL** 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 **BIAXIN® XL**.

Serious Warnings and Precautions

- **BIAXIN® XL should not be used in pregnancy especially during the first 3 months. If there are no other medicines you can take for your infection, your doctor may give you BIAXIN® XL. If this happens, they will discuss the risks to your baby with you. Talk to your doctor before taking BIAXIN® XL if you are pregnant or think you might be pregnant.**
- **Taking BIAXIN® XL along with certain other drugs may lead to serious safety issues. Talk to your doctor about all the medicines you take.**

What is BIAXIN® XL used for?

BIAXIN® XL is used to treat certain infections like pneumonia, bronchitis and infections of the sinuses and throat that are caused by bacteria.

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

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

How does BIAXIN® XL work?

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

What are the ingredients in BIAXIN® XL?

Medicinal ingredients: Clarithromycin.

Non-medicinal ingredients: Cellulosic polymers, lactose monohydrate, magnesium stearate, propylene glycol, Quinoline Yellow Lake E104, sorbitan monooleate, talc, titanium dioxide and vanillin.

BIAXIN® XL comes in the following dosage forms:

500 mg extended-release tablets.

Do not use BIAXIN® XL if:

- You are allergic to clarithromycin or any of the other ingredients in BIAXIN® XL.

- You are allergic to another medicine called erythromycin or any other medicines from a class of antibiotics called macrolides (such as azithromycin or telithromycin).
- You are taking any of the following medications:
 - Ergotamine, dihydroergotamine (for migraine); Lovastatin, simvastatin (for high cholesterol); Ticagrelor (for cardiovascular disease); Saquinavir (treatment for HIV); Oral midazolam (for trouble sleeping or agitation); Pimozide (for schizophrenia); Colchicine (for gout); Domperidone (for gastrointestinal disorders).
 - Pimozide, ergotamine, dihydroergotamine and colchicine can interact with BIAXIN[®] XL, possibly leading to an irregular heartbeat. Deaths have occurred.
- You had liver problems after taking BIAXIN[®] XL in the past.
- You have severe liver failure in combination with kidney impairment.
- You have a history of heart disturbance or irregular heartbeat such as arrhythmias, QT prolongation or torsades de pointes.
- You have hypokalaemia (low potassium levels in the blood).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take BIAXIN[®] XL. Talk about any health conditions or problems you may have, including if you:

- Have now or have had health problems in the past.
- Have or develop severe diarrhea as this may be a sign of a more serious condition.
- Have kidney problems.
- Have liver problems.
- Are taking medicines called digoxin (for heart failure); atorvastatin or pravastatin (for high cholesterol); or midazolam (a sedative).
- Are taking a medicine called quetiapine (for schizophrenia, bipolar depression). Serious and life-threatening side effects have occurred in people taking clarithromycin and quetiapine, including malignant neuroleptic syndrome (fever, rigid muscles, dizziness, fainting, and altered mental state). Your doctor will decide if you should take this medication.
- Are allergic to other medicines, foods, dyes, or preservatives.
- Have a hereditary problem of galactose intolerance, Lapp lactase insufficiency or glucose/galactose malabsorption since this product contains lactose.
- Are pregnant, trying to get pregnant or think you might be pregnant.

- You are breastfeeding or planning to breastfeed. Clarithromycin can get into your breastmilk and harm your baby.
- Have a condition called myasthenia gravis which is a chronic disease that causes muscle weakness. BIAXIN[®] XL may make your myasthenia gravis worse.
- Are taking clarithromycin and oral drugs for diabetes (such as gliclazide, glyburide) and / or with insulin as this can result in serious low blood sugar levels (hypoglycemia). Discuss with your doctor or pharmacist how you should monitor your blood sugar levels.
- Are taking warfarin, as there is a risk of serious bleeding with clarithromycin.
- Are taking triazolam, alprazolam or other benzodiazepines (midazolam). These should be used cautiously with clarithromycin due to the serious risk of effects on your brain and spinal cord.

Other warnings you should know about:

Use of antibiotics like clarithromycin have resulted in heart problems such as irregular heartbeat, torsades de pointes and QT prolongation sometimes leading to death. Talk to your doctor if you are elderly or have risk factors such as:

- Heart disease, heart problems or slow heartbeat.
- If you are taking other medicines which are known to cause serious disturbances in heart rhythm.
- If you have disturbances in the levels of salts (electrolytes) in your blood, such as low levels of magnesium (hypomagnesemia).

Development of antibiotic resistance (where the medicine no longer works to kill bacteria) has been seen in patients with HIV taking clarithromycin. To avoid this, you should always take your medicine as advised by your doctor.

Driving and using machines:

If you feel dizzy, confused or disorientated while taking BIAXIN[®] XL, do not drive or operate machines.

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 BIAXIN[®] XL:

- Alfentanil (used during surgery).
- Alprazolam, hexobarbital, phenobarbital, midazolam, triazolam (sedative medications).
- Amlodipine, diltiazem, verapamil calcium channel blockers often used for high blood pressure).
- Aripiprazole, pimozide, quetiapine, risperidone (for schizophrenia, bipolar depression).
- Atazanavir, indinavir, ritonavir, saquinavir, nevirapine, efavirenz, etravirine, zidovudine (treatments for HIV).
- Atorvastatin, lovastatin, pravastatin, rosuvastatin, simvastatin (for high cholesterol).
- Bromocriptine (used for problems with your pituitary gland and Parkinson's disease).

- Carbamazepine (for seizures, nerve pain or bipolar depression).
- Cilostazol, digoxin, quinidine, disopyramide, warfarin/acenocoumarol, ticagrelor (diseases of your blood vessels and heart).
- Colchicine (treatment for gout).
- Cyclosporine (used for psoriasis, rheumatoid arthritis and after organ transplant).
- Domperidone (used for gastrointestinal disorders).
- Ergotamine, dihydroergotamine (often used for migraine headaches).
- Fluconazole, itraconazole (for fungal infections).
- Insulin, nateglinide, pioglitazone, repaglinide, rosiglitazone (for diabetes).
- Lansoprazole, omeprazole (proton pump inhibitors for heart burn and reflux).
- Methylprednisolone (an anti-inflammatory).
- Phenytoin, valproic acid (treatment of seizures and epilepsy).
- Rifabutin, rifampin (treatments for infections).
- Sildenafil, tadalafil, vardenafil (treatments for erectile dysfunction).
- St. John's Wort (for depression).
- Tacrolimus (used after organ transplant).
- Theophylline (asthma and other lung problems).
- Tolterodine (treatment for overactive bladder).
- Vinblastine, ibrutinib (cancer treatment).

How to take BIAXIN® XL:

- Take BIAXIN® XL with food.
- Swallow BIAXIN® XL whole with a glass of water.
- Do not break, chew or crush the tablets.

Usual dose:

The usual adult dose is 2 x 500 mg tablets (1000 mg) every 24 hours for 5, 7 or 14 days.

Overdose:

Symptoms of BIAXIN® XL overdose are abdominal pain, vomiting, nausea and diarrhea.

If you think you have taken too much BIAXIN® XL, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

- If you miss a dose, take it as soon as you remember.
- If it is almost time for your next dose, do not take the missed dose.
- Take your next dose when you would normally take it.
- Never take a double dose to make up for a missed dose.

What are possible side effects from using BIAXIN® XL?

These are not all the possible side effects you may feel when taking BIAXIN® XL. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- abdominal pain
- abnormal taste
- diarrhea
- ear disorder (trouble hearing and ringing in your ears)
- flatulence
- indigestion
- headache
- nausea
- rash
- vomiting

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 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	
UNCOMMON Allergic reactions: itching, hives, rash, sore throat, fever, swelling, difficulty breathing, lightheadedness / dizziness, swelling of your tongue or throat, warm red skin or wheezing.			✓
Clostridium difficile colitis (bowel inflammation): severe diarrhea (bloody or watery) with or without fever, abdominal pain, or tenderness.		✓	
Irregular heartbeat			✓
Myasthenia gravis: muscle weakness, drooping eyelid, vision changes, difficulty chewing and swallowing, trouble breathing.			✓
Hepatitis (liver inflammation): abdominal pain, nausea, vomiting, yellowing of skin and eyes, dark urine.			✓

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.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 between 15 and 25°C in a tightly closed container. Protect from light. Do not use beyond the expiration date.

Keep out of the reach and sight of children.

If you want more information about BIAXIN® XL:

- 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://hc-sc.gc.ca/index-eng.php>); the manufacturer's website (www.mylan.ca), or by calling 1-844-596-9526

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Last Revised OCT 25 2018