

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

PrBIAXIN®
clarithromycin for oral suspension USP

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

Serious Warnings and Precautions

- **BIAXIN® 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®. If this happens, they will discuss the risks to your baby with you. Talk to your doctor before taking BIAXIN® if you are pregnant or think you might be pregnant.**
- **Taking BIAXIN® along with certain other drugs may lead to serious safety issues. Talk to your doctor about all the medicines you take.**

What is BIAXIN® used for?

BIAXIN® is used to treat certain infections like pneumonia (lung infection), otitis (middle ear infection), and pharyngitis (infections of the skin and throat) that are caused by bacteria.

It is used to treat mycobacterial infections. Mycobacteria are a group of bacteria that cause several diseases.

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

How does BIAXIN® work?

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

What are the ingredients in BIAXIN®?

Medicinal ingredients: Clarithromycin.

Non-medicinal ingredients: Carbopol, povidone, polymer, sucrose or sugar, maltodextrin, xanthan gum, silicon dioxide, potassium sorbate, citric acid, artificial and natural fruit flavour, castor oil, and titanium dioxide.

BIAXIN® comes in the following dosage forms:

125 mg / 5mL and 250 mg / 5mL) granules for oral suspension (provided in liquid form by your pharmacist).

Do not use BIAXIN® if:

- You / your child are allergic to clarithromycin or any of the other ingredients in BIAXIN®.
- You / your child are allergic to another medicine called erythromycin or any other medicines from a class of

antibiotics called macrolides (such as azithromycin or telithromycin).

- You / your child 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[®], possibly leading to an irregular heartbeat. Deaths have occurred.
- You / your child had liver problems after taking BIAXIN[®] in the past.
- You / your child have severe liver failure in combination with kidney impairment.
- You / your child have a history of heart disturbance or irregular heartbeat such as arrhythmias, QT prolongation or torsades de pointes.
- You/your child 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[®]. Talk about any health conditions or problems you may have, including if you:

- Or your child has now or has had health problems in the past.
- Or your child has or develops severe diarrhea as this may be a sign of a more serious condition.
- Or your child has kidney problems.
- Or your child has liver problems.
- Or your child are taking medicines called digoxin (for heart failure); atorvastatin or pravastatin (for high cholesterol); or midazolam (a sedative).
- Or your child 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/ your child should take this medication.
- Or your child are allergic to other medicines, foods, dyes, or preservatives.
- Have hereditary problems of fructose intolerance, glucose/galactose malabsorption or sucrose/maltase insufficiency since this product contains sucrose.
- Are pregnant, trying to get pregnant or think you might be pregnant.
- Are breastfeeding or planning to breastfeed. Clarithromycin can get into your breastmilk and harm your

baby.

- Or your child have a condition called myasthenia gravis which is a chronic disease that causes muscle weakness. BIAXIN[®] may make your myasthenia gravis worse.
- Or your child 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.
- Or your child are taking warfarin, as there is a risk of serious bleeding with clarithromycin.
- Or your child 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, have risk factors, or you / your child:

- Has heart disease, heart problems or slow heartbeat.
- Are taking other medicines which are known to cause serious disturbances in heart rhythm.
- 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[®], 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[®]:

- 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®:

- Always take it exactly how your / your child's doctor has told you.
- Your / your child's doctor will tell you how much BIAXIN® to take and when to take it.
- How much you / your child are prescribed will depend on the condition you / your child have.
- You / your child can take BIAXIN® with or without meals.
- BIAXIN® will be prepared in liquid form by your pharmacist.
- Shake prior to each use to ensure resuspension.

Usual dose:

The recommended daily dose of BIAXIN® is 15 mg / kg / day, in divided doses every 12 hours. The daily dose should not to exceed 1000 mg. The usual duration of treatment is for 5 to 10 days.

Overdose:

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

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

Missed Dose:

- If you / your child miss a dose, take / give it as soon as you remember.
- If it is almost time for your / your child's next dose, the missed dose should not be taken.
- Take / give to your child the next dose when you would normally take / give it.
- Never take / give to your child a double dose to make up for a missed dose.

What are possible side effects from using BIAXIN®?

These are not all the possible side effects you may feel when taking BIAXIN®. 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

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 reconstituted product between 15 and 30°C and use within 14 days. Do not refrigerate. Any reconstituted unused medication should be discarded after 14 days. The graduated syringe included in the package should be rinsed between uses. Do not leave syringe in bottle. Do not store reconstituted suspension in syringe.

Keep out of the reach and sight of children.

If you want more information about BIAXIN®:

- 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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