

## PART III: CONSUMER INFORMATION

### **Pr**BIAXIN BID<sup>®</sup> clarithromycin tablets, USP, film-coated

This leaflet is Part III of a three-part "Product Monograph" published when BIAXIN BID<sup>®</sup> 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 BID<sup>®</sup>. Contact your doctor or pharmacist if you have any questions about the drug.

#### **ABOUT THIS MEDICATION**

##### **What the medication is used for:**

BIAXIN BID<sup>®</sup> is used to treat certain infections caused by bacteria, such as pneumonia, bronchitis, infections of the sinuses, skin, and throat.

When used with other medications, it can treat infection caused by a bacterium called *Helicobacter pylori* (*H. pylori*) and reduce the risk of duodenal ulcer recurrence. A duodenal ulcer is a sore on the lining of the duodenum, which is the beginning of the small intestine.

It can also be prescribed to prevent and combat MAC disease in patients with HIV. MAC is a short word for *Mycobacterium avium* complex, the germs that cause MAC disease.

##### **What it does:**

BIAXIN BID<sup>®</sup> is an antibiotic that kills bacteria in your body.

##### **When it should not be used:**

Do not take BIAXIN BID<sup>®</sup> 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 BID<sup>®</sup> 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 BID<sup>®</sup>, possibly leading to an irregular heartbeat pattern; deaths have occurred.

\* no longer marketed in Canada.

Do not take BIAXIN BID<sup>®</sup> if you have ever developed liver problems after using BIAXIN BID<sup>®</sup>.

Do not use BIAXIN BID<sup>®</sup> if you have a history of heart disturbance or irregular heart beat (arrhythmias, QT prolongation, torsade de pointes).

##### **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, croscarmellose sodium, D&C Yellow No. 10, magnesium stearate, povidone, pregelatinized starch (250 mg only), propylene glycol, silicon dioxide, sorbic acid, sorbitan monooleate, stearic acid, talc, titanium dioxide and vanillin.

##### **What dosage forms it comes in:**

This medicine comes in:

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

#### **WARNINGS AND PRECAUTIONS**

##### **Serious Warnings and Precautions**

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

**Before taking BIAXIN BID<sup>®</sup>, 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 BID<sup>®</sup> 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 BID<sup>®</sup> 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 BID<sup>®</sup> (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 BID<sup>®</sup>, 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.

**Dual Therapy:** BIAXIN BID<sup>®</sup> + Omeprazole

The recommended dose is the following for 14 days:

- BIAXIN BID<sup>®</sup>: 500 mg every 8 hours
- Omeprazole: 40 mg once daily followed by 20 mg omeprazole once daily for 14 days

**MAC disease:**

The recommended dose of BIAXIN BID<sup>®</sup> for prevention and treatment of MAC disease is 500 mg every 12 hours.

Treatment of disseminated MAC infection (MAC infection spread through your whole body) in patients with HIV should continue for life if improvement of symptoms is observed.

**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 BID<sup>®</sup> 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.

**INTERACTIONS WITH THIS MEDICATION**

**Drugs that may interact with BIAXIN BID<sup>®</sup> 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 Adult Dose:**

BIAXIN BID<sup>®</sup> may be taken with or without meals.

Respiratory Tract or Skin Infections:

The usual dosage of BIAXIN BID<sup>®</sup> is 250 mg to 500 mg every 12 hours for 7 to 14 days.

Infections with *H. pylori*:

**Triple Therapy:** BIAXIN BID<sup>®</sup> + Omeprazole + Amoxicillin

The recommended dose is the following for 10 days:

- BIAXIN BID<sup>®</sup>: 500 mg every 12 hours
- Omeprazole: 20 mg once daily
- Amoxicillin: 1 g every 12 hours

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Like all medicines, BIAXIN BID<sup>®</sup> can cause side effects. The majority of side effects observed in clinical trials with BIAXIN BID<sup>®</sup> 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.

Serious side effects from BIAXIN BID<sup>®</sup> are not common.

If dizziness, confusion or disorientation occur while taking BIAXIN BID<sup>®</sup>, 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 BID<sup>®</sup>, contact your doctor or pharmacist.*

**HOW TO STORE IT**

Keep BIAXIN BID<sup>®</sup> 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](http://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<sup>™</sup> 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

This leaflet was prepared by Abbott Laboratories, Limited.

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