

PART III: CONSUMER INFORMATION

BIAXIN BID[®]

clarithromycin tablets, USP, film-coated

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

ABOUT THIS MEDICATION

What the medication is used for:

BIAXIN BID[®] 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 bacteria called *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[®] is an antibiotic that kills bacteria in your body.

When it should not be used:

Do not take BIAXIN BID[®] 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[®] if you are taking astemizole*, cisapride*, pimozide, terfenadine*, ergotamine, or dihydroergotamine. These medicines can interact, possibly leading to an irregular heartbeat pattern; deaths have occurred.

* no longer marketed in Canada.

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[®], 250 mg and 500 mg),
- extended-release tablets (BIAXIN[®] XL, 500 mg)
- liquid form (BIAXIN[®], 125 mg/5mL and 250 mg/5mL).

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

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

Before taking BIAXIN BID[®], 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[®] 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[®] 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, pimozide, ergotamine, dihydroergotamine, digoxin, or colchicine.
- if you have any unusual or allergic reaction (rash, difficulty breathing) to clarithromycin or any of the non-medicinal ingredients in BIAXIN BID[®] (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.

WHILE taking BIAXIN BID[®], 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.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with BIAXIN BID[®] includes:

Alfentanil, alprazolam, astemizole/terfenadine, atazanavir, atorvastatin, bromocriptine, carbamazepine, cilostazol, cisapride/pimozide, colchicine, cyclosporine, digoxin, disopyramide/quinidine, efavirenz, ergotamine/dihydroergotamine, fluconazole, hexobarbital, itraconazole, lansoprazole/omeprazole, lovastatin/simvastatin, methylprednisolone, midazolam/triazolam, nevirapine, phenytoin, rifabutin/rifampin, rifapentine*, ritonavir/indinavir, saquinavir, sildenafil, 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[®] may be taken with or without meals.

Respiratory Tract or Skin Infections:

The usual dosage of BIAXIN BID[®] is 250 mg to 500 mg every 12 hours for 7 to 14 days.

Infections with H. Pylori:

Triple Therapy: BIAXIN BID[®] + Omeprazole + Amoxicillin

The recommended dose is the following for 10 days:

- BIAXIN BID[®]: 500 mg every 12 hours
- Omeprazole: 20 mg once daily
- Amoxicillin: 1 g every 12 hours

Double Therapy: BIAXIN BID[®] + Omeprazole

The recommended dose is the following for 14 days:

- BIAXIN BID[®]: 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[®] 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:

Contact your doctor, pharmacist or local poison control centre if you have taken more than the recommended dose. Symptoms of BIAXIN BID[®] 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 BID[®] can cause side effects. The majority of side effects observed in clinical trials with BIAXIN BID[®] 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[®] are not common.

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[®], contact your doctor or pharmacist.

HOW TO STORE IT

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

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

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 866-234-2345

By toll-free fax: 866-678-6789

Online: www.healthcanada.gc.ca/medeffect

By email: CanadaVigilance@hc-sc.gc.ca

By regular mail:

Canada Vigilance National Office
Marketed Health Products Safety and
Effectiveness Information Bureau
Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Tunney's Pasture, AL 0701C
Ottawa ON K1A 0K9

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. 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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