

## PART III: CONSUMER INFORMATION

PrHp-PAC®

**lansoprazole delayed-release capsule  
clarithromycin tablets, USP, film-coated  
amoxicillin capsules**

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

### ABOUT THIS MEDICATION

#### What the medication is used for:

The components of Hp-PAC® can be used to 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.

#### What it does:

PREVACID® (lansoprazole) helps to lower the acidity of the stomach which helps the antibiotics, BIAXIN® BID (clarithromycin) and amoxicillin, to work better to kill the bacteria in your body and helps to heal the ulcer.

#### When it should not be used:

You should not take the components of Hp-PAC® if you have an allergy to lansoprazole, clarithromycin, amoxicillin, or to any of the nonmedicinal ingredients in PREVACID®, BIAXIN® BID or amoxicillin capsules (see What the important nonmedicinal ingredients are below).

Do not take BIAXIN® BID if you are:

- sensitive to erythromycin, or other antibacterial agents of the same family;
- taking astemizole\*, cisapride\*, pimizole, terfenadine\*, ergotamine, or dihydroergotamine. These medicines can interact, possibly leading to an irregular heartbeat pattern; deaths have occurred.

\* no longer sold in Canada.

Do not take AMOXICILLIN Capsules if you have, or think you have, mononucleosis.

#### What the medicinal ingredient is:

lansoprazole; clarithromycin; amoxicillin trihydrate

#### What the important nonmedicinal ingredients are:

The nonmedicinal ingredients in PREVACID® are the following: cellulosic polymers, colloidal silicon dioxide, D & C Red No. 28, FD & C Blue No. 1, FD & C Red No. 40, gelatin, magnesium carbonate, methacrylic acid copolymer, starch, talc, sugar spheres, sucrose, polyethylene glycol, polysorbate 80, and titanium dioxide.

The nonmedicinal ingredients in BIAXIN® BID are the following: cellulosic polymers, croscarmellose sodium, D&C Yellow No. 10, magnesium stearate, povidone, propylene glycol, silicon dioxide, sorbic acid, sorbitan monooleate, stearic acid, talc, titanium dioxide and vanillin.

The nonmedicinal ingredients in the AMOXICILLIN Capsules are the following: colloidal silicon dioxide, D&C Yellow No. 10, dry-flo starch, FD&C Blue No. 1, FD&C Red No. 3, FD&C Red No. 40, FD&C Yellow No. 6, gelatin, magnesium stearate, sodium lauryl sulfate, talc and titanium dioxide.

#### What dosage forms it comes in:

The components of each daily blister pack of Hp-PAC® are as follows:

- PREVACID®: 2 x 30 mg capsules
- BIAXIN® BID: 2 x 500 mg tablets
- Amoxicillin: 4 x 500 mg capsules

Each box contains 7 daily blister packs.

### 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.

Serious allergic reactions (anaphylaxis), including death, have occurred in patients using penicillins (such as amoxicillin). AMOXICILLIN Capsules should not be used if you are allergic to penicillin as it may cause severe allergic reactions.

BEFORE you use Hp-PAC® 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 a malignant gastric ulcer;

- if you have liver problems;
- if you are taking astemizole, terfenadine, cisapride (not currently marketed in Canada), pimoziide, ergotamine, dihydroergotamine, digoxin, or colchicine;
- if you have any unusual or allergic reaction (rash, difficulty breathing) to lansoprazole, the antibiotics clarithromycin, amoxicillin, or penicillin, any of the nonmedicinal ingredients in PREVACID<sup>®</sup>, BIAXIN<sup>®</sup> BID and AMOXICILLIN Capsules (see What the important nonmedicinal ingredients are), other medicines, foods, dyes, or preservatives.;
- if you are pregnant, trying to get pregnant or are breast-feeding.

Before taking BIAXIN<sup>®</sup> BID, tell your doctor or pharmacist:

- if you have liver or kidney disease. You may not be able to take clarithromycin. Talk to your doctor if BIAXIN<sup>®</sup> 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 should follow closely the prescribed regimen.

## INTERACTIONS WITH THIS MEDICATION

### Drugs that may interact with PREVACID<sup>®</sup> include:

- ampicillin esters
- atazanavir
- digoxin
- iron salts
- ketoconazole
- sucralfate
- theophylline
- warfarin

### Drugs that may interact with BIAXIN<sup>®</sup> BID include:

Alaprazolam, alfentanil, astemizole/terfenadine, atorvastatin, bromocriptine, carbamazepine, cilostazol, cisapride/pimoziide, colchicine, cyclosporine, digoxin, disopyramide/quinidine, ergotamine/dihydroergotamine, fluconazole, hexobarbital, lansoprazole/omeprazole, lovastatin/simvastatin, methylprednisolone, midazolam/triazolam, phenytoin, rifabutin/rifampin, ritonavir/indinavir, sildenafil, tacrolimus, theophylline, valproate, vinblastine, warfarin/acenocoumarol, zidovudine and drugs metabolized by cytochrome P450 system.

## PROPER USE OF THIS MEDICATION

### Usual Dose:

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

The recommended dose is the following for 7, 10 or 14 days:

- PREVACID<sup>®</sup>: 30 mg every 12 hours
- BIAXIN<sup>®</sup> BID: 500 mg every 12 hours
- Amoxicillin: 1 g (2 x 500 mg) every 12 hours

PREVACID<sup>®</sup> should be taken prior to breakfast and another meal. You should not chew or crush PREVACID<sup>®</sup> capsules. PREVACID<sup>®</sup> capsule should be swallowed whole with sufficient water.

### Overdose:

Contact your doctor or pharmacist if you have taken more than the recommended dose. Symptoms of BIAXIN<sup>®</sup> BID overdose are abdominal pain, vomiting, nausea, and diarrhea.

### Missed Dose:

If you miss a dose, take it as soon as you can. If it is almost time for your next dose, take only that dose. Do not take double or extra doses.

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, the components of Hp-PAC<sup>®</sup> can cause side effects. However, most people do not have any side effects at all.

### Hp-PAC<sup>®</sup>:

The following side effects were observed most often when all three components of Hp-PAC<sup>®</sup> were taken at the same time: abnormal taste, diarrhea, and headache. Talk to your doctor or pharmacist if any of these side effects persist or become bothersome.

### PREVACID<sup>®</sup>:

The following side effects have been reported (occurring between 1% and 10% in clinical trials): arthralgia (muscle pain), belching, constipation, diarrhea, dizziness, dry mouth, gas, headache, indigestion, insomnia, nausea, rash, vomiting, weakness. Talk to your doctor or pharmacist if any of these side effects persist or become bothersome.

If the following symptoms appear, consult your physician: bladder infection (pain, burning sensation upon urination) and upper respiratory tract infections (e.g., bronchitis, sinusitis, runny nose, sore throat).

Serious side effects from lansoprazole are not common.

### BIAXIN<sup>®</sup> BID:

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

**AMOXICILLIN:**

Like all medicines, amoxicillin can cause side effects. The following side effects have been reported: diarrhea, nausea, rash and vomiting. Talk to your doctor or pharmacist if any of these side effects persist or become bothersome.

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
<b>Hp-PAC®</b>				
Uncommon	Severe diarrhea			✓
<b>PREVACID®</b>				
Uncommon (occurring between 0.2% and 1% in clinical trials)	Abdominal pain		✓	
	Severe diarrhea accompanied with blood and/or mucous			✓
<b>BIAXIN® BID</b>				
Uncommon	Allergic reactions*			✓
	Severe diarrhea		✓	
	Severe abdominal cramps		✓	
	Irregular heart beat			✓
<b>AMOXICILLIN</b>				
Uncommon	Allergic reactions*			✓

\*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 Hp-PAC®, contact your doctor or pharmacist.*

**HOW TO STORE IT**

Keep Hp-PAC® and all other medicines out of reach of children.

Store at room temperature (15 - 25°C / 59 - 77°F) in the original package. Protect from light and moisture. Do not use beyond the expiration date.

**REPORTING SUSPECTED SIDE EFFECTS**

**To monitor drug safety, Health Canada 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 Health Canada by:**

Toll-free telephone: 1-866-234-2345  
 Toll-free fax: 1-866-678-6789  
 By email: [cadrmpp@hc-sc.gc.ca](mailto:cadrmpp@hc-sc.gc.ca)

**By regular mail:**  
 National AR Centre  
 Marketed Health Products Safety and Effectiveness Information Division  
 Marketed Health Products Directorate  
 Tunney's Pasture, AL 0701C  
 Ottawa ON K1A 0K9

*NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.*

**MORE INFORMATION**

This document plus the full Product Monograph, prepared for health professionals can be found at: <http://www.abbott.com> or by contacting the sponsor, Abbott Laboratories, Limited, Saint-Laurent, Qc H4S 1Z1 at: 1-800-699-9948

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