PART III: CONSUMER INFORMATION

**Hp-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 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 delayed-release capsules) 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, to other beta-lactam antibiotics (e.g. penicillin, cephalosporin), or to any of the nonmedicinal ingredients in PREVACID®, BIAXIN BID® or AMOXICILLIN Capsules (see What the important non-medicinal ingredients are below).

Do not take BIAXIN BID® if you:
- are sensitive to erythromycin, or other antibacterial agents of the same family;
- have ever developed liver problems after using BIAXIN BID®.
- suffer from severe liver failure in combination with kidney impairment.
- have a history of heart disturbance or irregular heartbeat (arrhythmias, QT prolongation, torsades de pointes).
- have hypokalaemia (low potassium levels in the blood).
- are taking astemizole*, cisapride*, colchicine, pimozide, terfenadine*, ergotamine, dihydroergotamine, lovastatin, oral midazolam, ranolazine*, simvastatin, or ticagrelor. These medicines can interact, possibly leading to an irregular heartbeat pattern; deaths have occurred.

Do not take AMOXICILLIN Capsules if you:
- have, or think you have, mononucleosis;
- have ever had an unusual hypersensitivity or allergic reaction to penicillin or to any other component of this product.

What the medicinal ingredient is:
lansoprazole, clarithromycin and amoxicillin trihydrate

What the important non-medicinal ingredients are:
PREVACID® 30 mg capsules contain colloidal silicon dioxide, D&C Red No. 28, FD&C Blue No. 1, FD&C Red No. 40, gelatin, hydroxypropyl cellulose, low substituted hydroxypropyl cellulose, magnesium carbonate, methacrylic acid copolymer, polyethylene glycol, polysorbate 80, starch, sucrose, sugar spheres, talc, and titanium dioxide.

BIAXIN BID® 500 mg tablets contain: celluloseic polymers, croscarmellose sodium, D&C Yellow No. 10, magnesium stearate, povidone, propylene glycol, silicon dioxide, sorbic acid, sorbitan monoleate, stearic acid, talc, titanium dioxide and vanillin.

AMOXICILLIN 500 mg capsules contain colloidal silicon dioxide, ECG size #0, dry-flo starch, magnesium stearate, sodium lauryl sulfate, talc.

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, cephalosporin and other antibacterial agents of the same family, 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 experience any cardiovascular (e.g., heart) or neurological (e.g., brain) symptoms including palpitations (rapid heartbeat), dizziness, seizures, and teta (muscle condition with symptoms such as twitching, spasms, cramps and convulsions) as these may be signs of hypomagnesemia (low magnesium levels in the body);
- if you are taking astemizole*, terfenadine*, cisapride* (* not currently marketed in Canada), atorvastatin, midazolam, pimozide, pravastatin, ergotamine, dihydroergotamine, digoxin, or clocicline;
- if you are taking HIV protease inhibitors (e.g., atazanavir, nelfinavir) as your doctor may recommend that these medications should not be taken at the same time as PREVACID®;
- if you have any unusual or allergic reaction (rash, difficulty breathing) to lansoprazole, the antibiotics clarithromycin, amoxicillin, to other beta-lactam antibiotics (e.g., penicillin, cephalosporin), or to any of the nonmedicinal ingredients in PREVACID®, BIAXIN 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, breast-feeding or planning to breastfeed;
- if you are taking anticoagulants. Advise your doctor or pharmacist of any signs of bleeding including prolonged bleeding from cuts, increased menstrual flow, vaginal bleeding, nosebleeds, bleeds from gums brushing, unusual bleeding or bruising, red or brown urine or red or black stools;
- if you have blood problems such as leukopenia (low white blood cell count) neutropenia (low blood cell count).

PREVACID® may help your acid-related symptoms, but you could still have serious stomach problems. Talk to your doctor.

Under rare circumstances, supervised by your doctor, proton pump inhibitors might be used for long periods.

You should take PREVACID® exactly as prescribed, at the lowest dose possible for your treatment and for the shortest time needed.

People who take multiple daily doses of proton pump inhibitor medicines for a long period of time (a year or longer) may have an increased risk of fractures of the hip, wrist or spine. Talk to your doctor about your risk of bone fracture if you take PREVACID®.

Long term use of proton pump inhibitors may prevent normal absorption of Vitamin B12 from the diet and could lead to Vitamin B12 deficiency. Talk to your doctor.

Antibiotic resistance has developed in those taking clarithromycin. This makes the medication less effective or ineffective the next time you need this antibiotic. To reduce the chances of developing resistance, take the medicine exactly as your doctor has prescribed.

WHILE taking BIAXIN BID®, contact your doctor if:

- you develop symptoms of myasthenia gravis (a muscle disease) 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.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with PREVACID® include:

- ampicillin esters
- HIV protease inhibitors (e.g., atazanavir, nelfinavir)
- clopidogrel
- digoxin
- iron salts
- ketoconazole
- methotrexate
- sucralfate
- tacrolimus
- theophylline
- warfarin

Drugs that may interact with BIAXIN BID® include:

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/pravastatin/ simvastatin, methylprednisolone, midazolam/triazolam, nateglinide, nevirapine, phenobarbital, phenytoin, pioglitazone, ranolazine*, repaglinide, rifabutin/ritampin, rifapentine*, ritonavir/indinavir, rosiglitazone, rosuvastatin, saquinavir, sildenafil, St. John’s Wort (Hypericum perforatum), tacrolimus, tadalafl, ticagrelor, theophylline, tolterodine, valproic acid, vardenafil, verapamil, vinblastein, warfarin/acenocoumarol, zidovudine and drugs metabolized by cytochrome P450 system.

* not marketed in Canada.
Drugs that may interact with AMOXICILLIN include:

Methotrexate (anti-cancer agent), probenecid (gout treatment), tetracyclines (antibiotics), oral contraceptives, anticoagulants (e.g., warfain).

PROPER USE OF THIS MEDICATION

Usual Dose:

The recommended dose of Hp-PAC® is the following for 7, 10 or 14 days:

- PREVACID®: 30 mg every 12 hours
- BIAxin BID®: 500 mg every 12 hours
- Amoxicillin: 1000 mg (2 x 500 mg) every 12 hours

PREVACID® should be taken prior to breakfast and another meal. You should not chew or crush PREVACID® capsules.

PREVACID® capsules should be swallowed whole with sufficient water.

Your doctor may order periodic blood tests if longer therapy is prescribed.

Overdose:

In case of drug overdose, contact your healthcare professional, hospital emergency department or regional poison control centre, even if there are no symptoms.

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

Hp-PAC®

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

The following side effects were observed most often when all three components of Hp-PAC® 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®

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 PREVACID® are not common.

Treatment in combination with antibiotics

If you experience symptoms such as severe (bloody or repeated watery) diarrhea, with or without fever, abdominal pain or tenderness, you may have bowel inflammation cause by bacterial infection (Clostridium difficile). If this happens, stop taking the drug combination and call your healthcare professional immediately.

BIAxin BID®

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.

If dizziness, confusion or disorientation occur while taking BIAxin BID®, do not drive or operate machinery.

AMOXICILLIN

The following side effects have been reported: diarrhea, nausea, skin rashes and vomiting. Talk to your doctor or pharmacist if any of these side effects persist or become bothersome.
## SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

<table>
<thead>
<tr>
<th>Symptom / effect</th>
<th>Talk with your doctor or pharmacist</th>
<th>Stop taking drug and call your doctor or pharmacist</th>
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<tbody>
<tr>
<td><strong>Hp-PAC®</strong></td>
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<tr>
<td>Uncommon</td>
<td>Severe diarrhea</td>
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<td><strong>PREVACID®</strong></td>
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<tr>
<td>Uncommon (occurring between 0.2% and 1% in clinical trials)</td>
<td>Abdominal pain</td>
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<td>Severe diarrhea accompanied with blood and/or mucous</td>
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<tr>
<td><strong>BIAXIN BID®</strong></td>
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</tr>
<tr>
<td>Uncommon</td>
<td>Allergic reactions*</td>
<td>✅</td>
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<tr>
<td></td>
<td>Severe diarrhea</td>
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<td>Severe abdominal cramps</td>
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<td>Irregular heart beat</td>
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<td><strong>AMOXICILLIN</strong></td>
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<tr>
<td>Common</td>
<td>Allergic reactions* (skin rash, skin eruption or other effect on the skin or eyes)</td>
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<tr>
<td>Uncommon</td>
<td>Gastrointestinal (nausea, vomiting, diarrhea, bloody stool)</td>
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<tr>
<td></td>
<td>Serious Allergic Reactions / Anaphylaxis (swollen nose, eyes, throat, difficulty breathing, and serious skin reactions such as blistering, peeling skin, rash)</td>
<td>✅</td>
</tr>
</tbody>
</table>

### Indicates severe symptoms

*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 and sight of children.

Store at room temperature (15 - 25°C) in the original package. Protect from light and moisture. 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 online at: 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™ 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

The most recent version of this document plus the full Product Monograph, prepared for health professionals can be found at:

http://www.mylan.ca
or by contacting the distributor, BGP Pharma ULC, Saint-Laurent, Qc H4S 1Z1 at:
1-844-596-9526

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