

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

**PATIENT MEDICATION INFORMATION**

**PrHp-PAC<sup>®</sup>**  
**lansoprazole delayed-release capsule**  
**clarithromycin tablets, USP, film-coated**  
**amoxicillin capsules**

Read this carefully before you start taking **Hp-PAC<sup>®</sup>** 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 **Hp-PAC<sup>®</sup>**.

**Serious Warnings and Precautions**

**Do not use BIAXIN BID<sup>®</sup> if you are pregnant or nursing, unless your doctor tells you. This may harm your fetus or infant.**

**Serious allergic reactions, including death, have occurred in those using penicillins (e.g., amoxicillin). Do not use AMOXICILLIN if you are allergic to penicillin, cephalosporin and similar antibiotics.**

**What is Hp-PAC<sup>®</sup> used for?**

Hp-PAC<sup>®</sup> is used to treat infection caused by bacteria called *H. pylori* and reduce the risk of ulcer recurrence in the small intestine.

**How does Hp-PAC<sup>®</sup> work?**

Hp-PAC<sup>®</sup> contains PREVACID<sup>®</sup>, BIAXIN BID<sup>®</sup>, and AMOXICILLIN. Prevacid reduces stomach acid. This helps the 2 antibiotics to kill bacteria. Reducing the bacteria helps heal the ulcer.

**What are the ingredients in Hp-PAC<sup>®</sup>?**

Medicinal ingredients: lansoprazole, clarithromycin and amoxicillin trihydrate

Non-medicinal ingredients:

PREVACID<sup>®</sup> 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<sup>®</sup> 500 mg tablets contain 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.

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

**Hp-PAC<sup>®</sup> comes in the following dosage forms:**

Each daily blister pack of Hp-PAC<sup>®</sup> contains:

- PREVACID<sup>®</sup>: 2 x 30 mg capsules
- BIAXIN BID<sup>®</sup>: 2 x 500 mg tablets
- Amoxicillin: 4 x 500 mg capsules

Each box contains 7 daily blister packs.

**Do not use Hp-PAC<sup>®</sup> if:**

Do not take Hp-PAC<sup>®</sup> if you have an allergy to:

- lansoprazole, clarithromycin, amoxicillin, penicillin, cephalosporin, erythromycin, or other similar antibiotics.
- any of the nonmedicinal ingredients in PREVACID<sup>®</sup>, BIAXIN BID<sup>®</sup> or AMOXICILLIN Capsules (see **What are the ingredients in Hp-PAC<sup>®</sup>?**).

Do not take PREVACID<sup>®</sup> if you:

- are taking rilpivirine.

Do not take BIAXIN BID<sup>®</sup> if you:

- have ever developed liver problems after using BIAXIN BID<sup>®</sup>.
- your kidneys are not functioning well and you have severe liver failure.
- 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, ticagrelor or saquinavir/ritonavir.

These medicines can interact, possibly leading to an irregular heartbeat pattern; deaths have occurred.

\* not marketed in Canada.

Do not take AMOXICILLIN Capsules if you:

- have, or think you have, mononucleosis.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Hp-PAC<sup>®</sup>. Talk about any health conditions or problems you may have, including:**

- about all health problems you have now or have had in the past;
- if you have or develop severe diarrhea. This may be a sign of a more serious condition;
- if you have kidney problems;
- if you have a stomach cancer;
- if you have liver problems;
- if you experience any palpitations (rapid heartbeat), dizziness, seizures, twitching, spasms, cramps and convulsions. These may be signs of low magnesium levels in the body;
- if you are taking atorvastatin, midazolam, pravastatin, digoxin, or colchicine;
- if you are taking other medications (see **The following may interact with Hp-PAC<sup>®</sup>**)
- if you are pregnant, trying to get pregnant, breast-feeding or planning to breastfeed;
- if you are taking blood thinners. Tell your doctor or pharmacist of signs of heavy bleeding or unusual bruising, including:
  - prolonged bleeding from cuts.
  - bleeding from nose or gums.
  - heavy menstruation.
  - red or brown urine.
  - red or black stools.
- if you have blood problems such as leukopenia (low white blood cell count) neutropenia (low blood cell count);
- if you are due to have a specific blood test (Chromogranin A).

**Other warnings you should know about:**

PREVACID<sup>®</sup> may help your acid-related symptoms. However you could still have serious stomach problems. Talk to your doctor if your problems continue.

Take PREVACID<sup>®</sup> exactly as your doctor tells you. You will use the lowest dose and shortest time suitable for your condition. Talk to your doctor if you have any concerns about your treatment.

Depending on your condition, your doctor may tell you to use PREVACID<sup>®</sup> for a longer period.

Using proton pump inhibitors like PREVACID<sup>®</sup> for a long time (every day for a year or longer) may increase risks of broken bones of the hip, wrist or spine. Talk to your doctor about this risk.

Long term use of proton pump inhibitors may also interfere with the absorption of Vitamin B<sub>12</sub> from the diet. This may cause a shortage of Vitamin B<sub>12</sub> in your body. Talk to your doctor.

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

**WHILE taking BIAXIN BID<sup>®</sup>, contact your doctor if you develop:**

- symptoms or worsening of the muscle disease, myasthenia gravis, such as:
  - muscle weakness that gets worse with activity.
  - muscle weakness that gets better with rest.
  - difficulty chewing, swallowing or breathing.
  - drooping eyelid, blurred or double vision.
- symptoms of liver inflammation (hepatitis) such as:
  - abdominal pain, nausea, vomiting.
  - yellowing of skin and eyes.
  - dark-coloured urine. Stop taking the drug immediately.

**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 Hp-PAC<sup>®</sup>:**

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

- ampicillin esters
- atazanavir
- nelfinavir
- saquinavir/ritonavir
- clopidogrel
- digoxin
- iron salts
- ketoconazole
- methotrexate
- sucralfate
- tacrolimus
- theophylline
- warfarin

Drugs that may interact with BIAXIN BID<sup>®</sup> 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/rifampin, rifapentine\*, ritonavir/indinavir, rosiglitazone, rosuvastatin, saquinavir, saquinavir/ritonavir, sildenafil, St. John's Wort (*Hypericum perforatum*), tacrolimus, tadalafil, ticagrelor, theophylline, tolterodine, valproic acid, vardenafil, verapamil, vinblastine, 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., warfarin).

### **How to take Hp-PAC<sup>®</sup>:**

Hp-PAC<sup>®</sup> consists of PREVACID<sup>®</sup>, BIAXIN BID<sup>®</sup>, and AMOXICILLIN.

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

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

### **Usual dose:**

The recommended dose of Hp-PAC<sup>®</sup> is:

- PREVACID<sup>®</sup>: 30 mg every 12 hours
- BIAXIN BID<sup>®</sup>: 500 mg every 12 hours
- Amoxicillin: 1000 mg (2 x 500 mg) every 12 hours

Duration of treatment may be 7, 10 or 14 days, as directed by your doctor.

### **Overdose:**

If you think you have taken too much Hp-PAC<sup>®</sup>, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, 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.

**What are possible side effects from using Hp-PAC<sup>®</sup>?**

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.

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.

Tell your doctor right away if you have any of these symptoms:

- New or worsening joint pain
- Rash on your cheeks or arms that gets worse in the sun

Serious side effects from PREVACID<sup>®</sup> or BIAXIN BID<sup>®</sup> are uncommon. Refer to the table below for serious side effects and what to do about them.

**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.

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).

**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 caused by bacterial infection (*Clostridium difficile*). If this happens, stop taking the drug combination and call your healthcare professional immediately.

**BIAXIN BID<sup>®</sup>**

The following adverse reactions were reported (occurring between 1% and 10% in clinical trials): abdominal pain, abnormal taste, diarrhea, ear disorder, flatulence, indigestion, headache, nausea, rash, vomiting.

If dizziness, confusion or disorientation occur while taking BIAXIN BID<sup>®</sup>, do not drive or operate machinery.

## AMOXICILLIN

The following side effects have been reported: diarrhea, nausea, skin rashes and 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	
<b>Hp-PAC<sup>®</sup></b>			
<b>UNCOMMON</b> Severe diarrhea			✓
<b>PREVACID<sup>®</sup></b>			
<b>UNCOMMON*</b> Abdominal pain		✓	
Severe diarrhea accompanied with blood and/or mucous			✓
<b>BIAXIN BID<sup>®</sup></b>			
<b>UNCOMMON</b> Allergic reactions <sup>†</sup>			✓
Severe diarrhea		✓	
Severe abdominal cramps		✓	
Irregular heart beat			✓
<b>AMOXICILLIN</b>			
<b>COMMON</b> Allergic reactions (itching, skin rash, skin eruption or other effect on the skin or eyes, lightheadedness/dizziness, fever, swelling, sore throat)			✓
<b>UNCOMMON</b> Gastrointestinal (nausea, vomiting, diarrhea, bloody stool)			✓
Serious Allergic Reactions / Anaphylaxis (swollen nose, eyes, throat, difficulty breathing, and serious skin reactions such as blistering, peeling skin, rash)			✓
Kidney disorder (excretion of crystals in the urine, crystalluria)			✓

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Liver disorder, yellowing of the skin and eyes (Jaundice), abdominal pain, nausea, cytolytic hepatitis (destruction of liver cells)			✓
Oral (glossitis- black “hairy” tongue and stomatitis, tooth discoloration in children (brown, yellow or gray staining)		✓	
Central Nervous System (dizziness, anxiety, insomnia, confusion, behavioural changes)		✓	
Blood problems such as leukopenia (low white blood cell count), neutropenia (low blood cell count)		✓	
* Uncommon: occurring between 0.2% and 1% in clinical trials			

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 help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

### 3 ways to report:

Online at [MedEffect](#);

By calling 1-866-234-2345 (toll-free);

By completing a Consumer Side Effect Reporting Form and sending it by:

- Fax to 1-866-678-6789 (toll-free), or
- Mail to:     Canada Vigilance Program  
                  Health Canada  
                  Postal Locator 1908C  
                  Ottawa, ON, K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

*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:

Keep Hp-PAC<sup>®</sup> and all other medicines out of reach and sight of children.

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

## If you want more information about Hp-PAC<sup>®</sup>:

- Talk to your healthcare professional

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

- [Health Canada website](#)
- [www.mylan.ca](http://www.mylan.ca)
- or by contacting the distributor, BGP Pharma ULC, Etobicoke, Ontario, M8Z 2S6 at:
- 1-844-596-9526

This leaflet was prepared by BGP Pharma ULC.

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