

## PATIENT COUNSELLING INFORMATION

### <sup>Rx</sup> Combipack of Clarithromycin Tablets, Pantoprazole Tablets & Amoxicillin Tablets

#### Pantop HP Kit™

**Read the entire leaflet carefully before you start taking this medicine:**

- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

#### 1. What is Pantop HP Kit™ and what is it used for?

Pantop HP Kit™ is a combipack of Clarithromycin Tablet, Pantoprazole Tablet and Amoxicillin Tablet. Pantop HP Kit™ is indicated for eradication of *Helicobacter pylori* in patients with active chronic gastritis, stomach ulcers and duodenal ulcers.

Pantoprazole is a selective “proton pump inhibitor”, a medicine which reduces the amount of acid produced in your stomach. It is used for treating acid-related diseases of the stomach and intestine. Clarithromycin belongs to a group of medicine called macrolide antibiotics. Antibiotics stop the growth of bacteria which cause infections. Amoxicillin is an antibiotic that belongs to a group of medicines called ‘penicillins’. Amoxicillin is used to treat infections caused by bacteria in different parts of the body.

#### 2. What you need to know before you take Pantop HP Kit™?

***Before taking Pantop HP Kit™ tell your doctor:***

- if you are allergic (hypersensitive) to Clarithromycin, Pantoprazole and Amoxicillin or any of the other ingredients of this medicine;
- if you are allergic to medicines containing other macrolide antibiotics, penicillins or proton pump inhibitors.
- if you are taking medicines called ergot alkaloid tablets (e.g. ergotamine or dihydroergotamine) or use ergotamine inhalers for migraine.
- if you are taking medicines called terfenadine or astemizole (widely taken for hay fever or allergies) or cisapride (for stomach disorders) or pimozide (for mental health problems) as combining these drugs can sometimes cause serious disturbances in heart rhythm. Consult your doctor for advice on alternative medicines.
- if you are taking lovastatin or simvastatin (HMG-CoA reductase inhibitors, commonly known as statins, used to lower levels of cholesterol (a type of fat) in the blood).
- if you are taking oral midazolam (a sedative).
- if you have abnormally low levels of potassium or magnesium in the blood (a condition known as hypokalaemia or hypomagnesaemia).
- if you are taking other medicines which are known to cause serious disturbances in heart rhythm.

- if you or someone in your family has a history of heart rhythm disorders (ventricular cardiac arrhythmia, including torsades de pointes) or abnormality of electrocardiogram (ECG, electrical recording of the heart) called “long QT syndrome”.
- if you have severe liver disease with kidney disease.
- if you are taking medicines called ticagrelor or ranolazine (for heart attack, chest pain or angina).
- if you are taking colchicine (usually taken for gout).
- if you are taking a medicine containing lomitapide.
- if you have ever had an allergic reaction to any antibiotic. This can include a skin rash or swelling of the face or throat.

### ***Warnings and precautions***

*Talk to your doctor if you:*

- have abnormally low levels of magnesium in your blood (hypomagnesaemia). If you have heart problems (e.g. heart disease, heart failure, an unusually slow heart rate).
- are pregnant or breast-feeding.
- have, or are prone to, fungal infections (e.g. thrush).
- have any liver or kidney problems.
- have severe liver problems.
- have reduced body stores or risk factors for reduced vitamin B12 and receive long-term treatment with Pantoprazole. As with all acid reducing agents, Pantoprazole may lead to a reduced absorption of vitamin B12.
- are taking HIV protease inhibitors such as atazanavir (for the treatment of HIV-infection) at the same time as Pantoprazole.
- are taking a proton pump inhibitor like Pantoprazole, especially over a period of more than one year; it may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).
- are on Pantoprazole for more than three months; it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.
- have ever had a skin reaction after treatment with a medicine similar to Pantoprazole that reduces stomach acid.
- get a rash on your skin, especially in areas exposed to the sun, as you may need to stop your treatment with Pantoprazole. Remember to also mention any other ill-effects like pain in your joints.
- are due to have a specific blood test (Chromogranin A).
- have glandular fever (fever, sore throat, swollen glands and extreme

- tiredness).
- have kidney problems.
- are not urinating regularly.

***Pregnancy, breast-feeding and fertility***

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

**Driving and using machines**

Pantop HP Kit™ has no or negligible influence on the ability to drive and use machines. If you experience side effects like dizziness or disturbed vision, you should not drive or operate machines.

**Other medicines and Pantop HP Kit™:**

Tell your doctor if you are taking, have recently taken or might take any of the following medicines as your dose may need to be changed or you may need to have regular tests performed.

- Digoxin, disopyramide or quinidine (for heart problems)
- Carbamazepine, valproate, phenobarbital or phenytoin (for epilepsy)
- Atorvastatin, rosuvastatin (HMG-CoA reductase inhibitors, commonly known as statins, are used to lower levels of cholesterol (a type of fat) in the blood). Statins can cause rhabdomyolysis (a condition which cause the breakdown of muscle tissue which can result in kidney damage) and signs of myopathy (muscle pain or muscle weakness) should be monitored.
- Theophylline (used in patients with breathing difficulties such as asthma)
- Triazolam, alprazolam or intravenous or oromucosal midazolam (sedatives)
- Cilostazol (for poor circulation)
- Methylprednisolone (a corticosteroid)
- Warfarin or any other anticoagulant e.g. dabigatran, rivaroxaban, apixaban (for thinning the blood)
- Nateglinide, pioglitazone, repaglinide, rosiglitazone or insulin (used to lower blood glucose levels)
- Gliclazide or glimepiride (sulphonylureas used in the treatment of type II diabetes)
- Vinblastine (for treatment of cancer)
- Ciclosporin, sirolimus or tacrolimus (immune suppressants)
- Etravirine, efavirenz, nevirapine, ritonavir, zidovudine, atazanavir, saquinavir (anti-viral drugs used in the treatment of HIV)
- Rifampicin, rifapentine, fluconazole, itraconazole or rifabutin (used for treatment of certain bacterial infections)
- Tolterodine (for overactive bladder)
- Verapamil, amlodipine, diltiazem (for high blood pressure)
- Sildenafil, vardenafil and tadalafil (for impotence in adult males or for use in pulmonary arterial hypertension (high blood pressure in the blood vessels of the lung))
- St John's Wort (a herbal product used to treat depression)

- Quetiapine or other antipsychotic medicines
- Other macrolide medicines
- Lincomycin and clindamycin (lincosamides – a type of antibiotic)
- Medicines such as ketoconazole, itraconazole and posaconazole (used to treat fungal infections) or erlotinib (used for certain types of cancer) because Pantoprazole may stop these and other medicines from working properly.
- Warfarin and phenprocoumon, which affect the thickening, or thinning of the blood. You may need further checks.
- Medicines used to treat HIV-infection, such as atazanavir.
- Methotrexate (used to treat rheumatoid arthritis, psoriasis, and cancer) – if you are taking methotrexate your doctor may temporarily stop your Pantoprazole treatment because Pantoprazole can increase levels of methotrexate in the blood.
- Fluvoxamine (used to treat depression and other psychiatric diseases) – if you are taking fluvoxamine your doctor may reduce the dose.
- Rifampicin (used to treat infections).
- St John’s wort (*Hypericum perforatum*) (used to treat mild depression).
- If you are taking allopurinol (used for gout) with Amoxicillin, it may be more likely that you will have an allergic skin reaction.
- If you are taking probenecid (used for gout), your doctor may decide to adjust your dose of Amoxicillin.
- If you are taking medicines to help stop blood clots (such as warfarin), you may need extra blood tests.
- If you are taking other antibiotics (such as tetracycline), Amoxicillin may be less effective.
- If you are taking methotrexate (used for the treatment of cancer and severe psoriasis) Amoxicillin may cause an increase in side effects.

Please tell your doctor if you are taking oral contraceptive pills and if diarrhea or vomiting occurs, as you may need to take extra contraceptive precautions such as using a condom.

### 3. How to take Pantop HP Kit™?

Always use this medicine exactly as your doctor has told you.

The recommended dose of Pantop HP Kit™ is one tablet each of Clarithromycin 500 mg, Pantoprazole 40 mg and Amoxicillin 750 mg twice daily for 7-14 days.

**Method of administration:** The tablets should not be chewed or crushed, and should be swallowed whole with water.

#### **If you take more Pantop HP Kit™ than you should**

If you have taken more dose of this medicine, than you should, talk to your doctor or nearest hospital emergency department immediately. You may require medical attention. This is important even if you feel well.

### **If you forget to take Pantop HP Kit™**

Do not take a double dose to make up for a forgotten dose, as you would not substitute the missing amount, but you risk an overdosing. Continue the treatment according to the instructions.

If you have any further questions on the use of this medicine, ask your doctor.

### **4. What are the possible side effects of Pantop HP Kit™?**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common side effects may include: Nausea, vomiting, abdominal pain, diarrhea, constipation, dyspepsia, dry mouth, headache, benign polyps in the stomach, heartburn, skin rash, discomfort, injection site pain & inflammation.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects.

### **5. How to store Pantop HP Kit™?**

**Store protected from light and moisture, at a temperature not exceeding 30°C.**

Keep out of reach of children.

Do not use this medicine after the expiry date which is stated on the container. The expiry date refers to the last day of that month.

**Date of revision:** February 14, 2022

*For further information please write to:*



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