APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

PANTOPRAZOLE 40 mg PD tablets

Pantoprazole

PANTOPRAZOLE 40 mg PD contains mannitol 141.0 mg.

Read all of this leaflet carefully before you start taking

PANTOPRAZOLE 40 mg PD

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other healthcare provider.
- PANTOPRAZOLE 40 mg PD has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What PANTOPRAZOLE 40 mg PD is and what it is used for

Pantoprazole is a proton pump inhibitor used to treat certain conditions in which there is too much acid in the stomach.

PANTOPRAZOLE 40 mg PD is used for:

- the treatment of duodenal ulcers, gastric ulcers and heartburn
- the treatment of Zollinger-Ellison Syndrome (a rare disorder that causes tumours in the pancreas and duodenum and ulcers in the stomach and duodenum).

2. What you need to know before you take PANTOPRAZOLE 40 mg PD

Do not take PANTOPRAZOLE 40 mg PD:

- if you are hypersensitive (allergic) to pantoprazole or any of the other ingredients of PANTOPRAZOLE 40 mg PD tablets (see section 6)
- if your liver function is impaired
- PANTOPRAZOLE 40 mg PD should not be given to children
- if you are taking atazanavir (a medicine used in the treatment of HIV).

Warnings and precautions

Take special care with PANTOPRAZOLE 40 mg PD:

- if you have impaired kidney function
- if you are taking warfarin (medicine that reduces the risk of blood clotting)
- if you have liver disease
- if you have low levels of magnesium in your blood
- tell your doctor if you are currently being treated or have a history of any malignancies (cancer or tumour) in the stomach area, or you think you have signs of stomach cancer (symptoms include weight loss, dark stools, loss of appetite, feeling full or a sensation of a lump in your stomach)

- if you have a history of a Vitamin B_{12} deficiency and receive long-term treatment (e.g. longer than 3 years) with PANTOPRAZOLE 40 mg PD. As with all acid reducing agents, PANTOPRAZOLE 40 mg PD may lead to a reduced absorption of vitamin B_{12}
- PANTOPRAZOLE 40 mg PD may be associated with an increased risk of *Clostridium difficile* associated diarrhoea (CDAD). If you develop diarrhoea that does not improve, contact your doctor or healthcare professional as soon as possible
- if you develop diarrhoea that does not improve (contact your doctor or health care professional as soon as possible) because PANTOPRAZOLE 40 mg PD has been associated with a small increase in infectious diarrhoea
- if you are over 50 years of age or when you take PANTOPRAZOLE 40 mg PD for a long period of time or in high doses, it may cause a low magnesium level in the body and cause an increase in risk of bone fractures in the hip, wrist or spine

- if you are on pantoprazole, as in PANTOPRAZOLE 40 mg PD, 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 or 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
- if you are taking HIV protease inhibitors such as atazanavir (for the treatment of HIV-infection) at the same time as pantoprazole, ask your doctor for specific advice
- if you take PANTOPRAZOLE 40 mg PD on a long-term basis (longer than 1 year), your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor
- if you get a rash on your skin, especially in areas exposed to the sun, tell your doctor as soon as you can, as you may need to stop your treatment with PANTOPRAZOLE 40 mg PD. Remember to also mention any other ill-effects like pain in your joints

- if you are due to have a specific blood test (Chromogranin A) PANTOPRAZOLE 40 mg PD treatment should be stopped for at least 5 days before Chromogranin A (CgA) measurements are taken and may require a further test 14 days after stopping therapy with PANTOPRAZOLE 40 mg PD.

Other medicines and PANTOPRAZOLE 40 mg PD

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines).

Some medicines that may be affected by PANTOPRAZOLE 40 mg PD are:

- certain medicines used to treat fungal infections, such as ketoconazole
- atazanavir, a compound found in anti-viral medicines. PANTOPRAZOLE 40 mg PD may therefore not be given to you, if you are also taking medicines containing atazanavir. (see Do not take PANTOPRAZOLE 40 mg PD)
- medicines to thin your blood, such as warfarin. PANTOPRAZOLE 40 mg PD may alter the effect of these medicines so your health care provider will want to monitor how well your blood clots

- methotrexate (high doses used in the treatment of certain cancers). PANTOPRAZOLE 40 mg PD may increase the levels of this medicine and possibly lead to methotrexate toxicity
- fluvoxamine (used to treat depression and other psychiatric diseases) – if you are taking fluvoxamine your doctor may reduce the dose
- St John's wort (*Hypericum perforatum*) (used to treat mild depression)
- the active ingredient, pantoprazole, is metabolised by certain liver enzymes, which may interact with other medicines or compounds which are also metabolised by these enzymes.

PANTOPRAZOLE 40 mg PD with food and drink

Take PANTOPRAZOLE 40 mg PD tablets immediately before a meal, preferably in the morning.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using PANTOPRAZOLE 40 mg PD.

Safety in pregnancy and breastfeeding has not been established.

You should not take PANTOPRAZOLE 40 mg PD if you are pregnant or breastfeeding your baby.

There is no data on fertility in humans with PANTOPRAZOLE 40 mg PD.

Driving and using machines

PANTOPRAZOLE 40 mg PD tablets may cause blurred vision or dizziness, which may impair your ability to drive or operate machinery. You should refrain from driving or using machinery until you know how PANTOPRAZOLE 40 mg PD affects you.
It is not always possible to predict to what extent PANTOPRAZOLE 40 mg PD may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which PANTOPRAZOLE 40 mg PD affects them.

PANTOPRAZOLE 40 mg PD contains sodium and mannitol

PANTOPRAZOLE 40 mg PD contains sodium. Your doctor will take this into account if you are on a sodium controlled diet.
PANTOPRAZOLE 40 mg PD contains mannitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking PANTOPRAZOLE 40 mg PD.

3. How to take PANTOPRAZOLE 40 mg PD

Do not share medicines prescribed for you with any other person.

Always take/use PANTOPRAZOLE 40 mg PD exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

PANTOPRAZOLE 40 mg PD tablets may be taken with food or on an empty stomach. PANTOPRAZOLE 40 mg PD tablets should be swallowed whole with a little water.

Do not crush, break or chew the tablet.

Your doctor will prescribe the appropriate dose according to your condition.

It may take several days before PANTOPRAZOLE 40 mg PD begins to relieve your symptoms. To help relieve your symptoms, antacids may be taken with PANTOPRAZOLE 40 mg PD tablets, unless your doctor has told you not to use them.

Your doctor will tell you how long your treatment with PANTOPRAZOLE 40 mg PD will last. Do not stop treatment early because your condition may worsen.

If you have the impression that the effect of PANTOPRAZOLE 40 mg PD is too strong or too weak, tell your doctor or pharmacist.

If you take more PANTOPRAZOLE 40 mg PD than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Take this leaflet and any remaining tablets with you, so that the doctor knows what the person has taken.

If you forget to take PANTOPRAZOLE 40 mg PD

If you missed a dose, take it as soon as you remember. If it is almost time for you next dose, skip the missed dose and continue to take the tablet at the usual time. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

PANTOPRAZOLE 40 mg PD can have side effects.

Not all side effects reported for PANTOPRAZOLE 40 mg PD are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using PANTOPRAZOLE 40 mg PD, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using PANTOPRAZOLE 40 mg PD and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to PANTOPRAZOLE 40 mg PD. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- stomach pain (severe)
- fever, rash, and enlarged kidneys sometimes with painful urination and lower back pain (serious inflammation of the kidneys), possibly leading to kidney failure

- blistering, loosening, peeling or redness of skin, Stevens-Johnson syndrome or other serious skin disorders such as Lyell-Syndrome, Erythema multiforme, (begins with flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters), drug rash with eosinophilia and systemic symptoms (DRESS) which is a type of drug allergy which can occur as a reaction to a large variety of medications
- yellow skin colour and/or yellow eyes, black tarry stools – symptoms of liver disease
- blurred vision.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- diarrhoea or constipation, abdominal pain, flatulence
- headache.

Less frequent side effects:

- low numbers of white cells in your blood
- high concentration of fatty products in the blood, increased body temperature

- trouble in sleeping, depression, disorientation, hallucination, confusion
- dizziness, distortion or complete lack of the sense of taste
- nausea and/or vomiting, dry mouth, bloating, stomach pain and discomfort
- other skin conditions
- muscle rigidness or stiffness, pain in joints or muscles, fracture of the hip, wrist or spine
- swelling and enlargement of breasts in men
- feeling of weakness, fatigue, malaise (feeling bad), swelling of the hands and feet
- a type of kidney problem (acute interstitial nephritis). Some people who take proton pump inhibitor (PPI) medicines, including PANTOPRAZOLE 40 mg PD, may develop a kidney problem called acute interstitial nephritis, that can happen at any time during treatment with PPI medicines. Call your doctor right away if you have a decrease in the amount that you usually urinate or if you have blood in your urine.

The following side effects have been reported but the frequency for them to occur is not known:

- inflammation in the large bowel, that causes persistent watery diarrhoea
- low levels of salt or magnesium or calcium in the blood
- muscle spasm as a consequence of electrolyte disturbance.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link:
https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/
https://www.sahpra.org.za/Publications/Index/8.
By reporting side effects, you can help provide more information on the safety of PANTOPRAZOLE 40 mg PD. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store PANTOPRAZOLE 40 mg PD

Store all medicines out of reach of children.

Store at or below 25 °C. Protect form moisture.

Store blister in the outer carton until required for use.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PANTOPRAZOLE 40 mg PD contains

The active substance is pantoprazole.

Each PANTOPRAZOLE 40 mg PD tablet contains pantoprazole sodium sesquihydrate equivalent to 40 mg pantoprazole.

The other ingredients are

Carmellose sodium, colloidal anhydrous silica, hypromellose, magnesium stearate, mannitol, methacrylic acid-ethyl acrylate copolymer, propylene glycol, sodium carbonate anhydrous, sodium starch glycolate type A, triethyl citrate and the colourants titanium dioxide (E171) and yellow iron oxide (E172).

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What PANTOPRAZOLE 40 mg PD looks like and contents of the pack

PANTOPRAZOLE 40 mg PD: Orangish, biconvex and oval gastro-resistant tablet. Diameter: 6,1 mm x 11,7 mm.

PANTOPRAZOLE 40 mg PD are packed in aluminium-polyamide-PVC/aluminium blister strips. 28 or 30 Tablets are packed in an outer carton.

Holder of Certificate of Registration

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