

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

PANTOCID OTC 20 mg gastro-intestinal tablets

Pantoprazole sodium sesquihydrate

Contains sugar

(5,0 mg lactose and 21,35 mg mannitol per tablet).

Read all of this leaflet carefully because it contains important information for you

PANTOCID OTC is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to take PANTOCID OTC carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share PANTOCID OTC with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 14 days.

What is in this leaflet

1. What PANTOCID OTC is and what it is used for.
2. What you need to know before you take PANTOCID OTC.
3. How to take PANTOCID OTC.
4. Possible side effects.
5. How to store PANTOCID OTC.
6. Contents of the pack and other information.

1. What PANTOCID OTC is and what it is used for

PANTOCID OTC contains the active ingredient pantoprazole, which belongs to a group of medicines called proton pump inhibitors. Proton pump inhibitors reduce the amount of acid produced in your stomach.

PANTOCID OTC is used for the short-term treatment of heartburn and excessive acid production in your stomach.

2. What you need to know before you take PANTOCID OTC

Do not take PANTOCID OTC:

- If you are hypersensitive (allergic) to pantoprazole or any of the other ingredients of PANTOCID OTC (listed in section 6).
- If you are pregnant or breastfeeding your baby.
- If you have serious liver problems.
- If you are taking atazanavir or nelfinavir (used to treat human immunodeficiency virus [HIV] infection).

PANTOCID OTC must not be given to children as it is not known if it is safe and effective for them.

Warnings and precautions

You must contact your medical practitioner for advice as soon as possible (especially if you have, or ever had, stomach ulcers or digestive tract operations) if you:

- are unintentionally losing weight
- notice you have very dark stools or blood in your stools
- have difficulty with, or have pain, when swallowing
- are vomiting blood
- have jaundice or hepatic impairment (a condition where your skin, the whites of your eyes and mucous membranes turn yellow and you feel very tired).

PANTOCID OTC, when taken in these cases, may relieve and hide the symptoms of a serious condition which needs treatment without delay.

Take special care and tell your doctor immediately if you notice any of the following symptoms:

- unintentional loss of weight;
- difficulty with or pain when swallowing;
- vomiting blood;
- look pale and feel weak (anaemia);
- you notice blood in your stools/black stools;
- you notice a decrease in the amount of that you urinate or blood in your urine;
- severe and/or persistent diarrhoea, especially if combined with nausea (feeling sick), vomiting (being sick), stomach cramps and/or fever, as PANTOCID OTC has been associated with a small increase in infectious diarrhoea.

Before taking PANTOCID OTC, consult your doctor:

- If you have severe liver problems.
- If you have reduced body stores or risk factors for reduced vitamin B12. PANTOCID OTC may lead to a reduced absorption of vitamin B12.
- If you have ever had a skin reaction after treatment with a medicine similar to PANTOCID OTC.
- If you have osteoporosis. Taking PANTOCID OTC long-term (for more than a year) may increase your risk of having wrist, hip and spine bone fractures, especially if you are elderly. Tell your doctor if you have osteoporosis as your risk may be higher.
- If you are taking medicines that treat HIV, such as atazanavir and nelfinavir that is protease inhibitors. PANTOCID OTC may reduce their effect on you.

- If you experience frequent urinating followed by a feeling of being unwell, nausea, and lack of appetite.

Children and adolescents

PANTOCID OTC must not be given to children as safety and efficacy have not been established.

Other medicines and PANTOCID OTC

Always tell your health care provider if you are taking any other medicine. This includes all complementary or traditional medicines.

Be careful to take PANTOCID OTC in combination with diazepam (medicine used to treat anxiety disorders) and phenytoin (medicine used to treat seizures) as PANTOCID OTC may increase the levels of diazepam and phenytoin in the body.

Medicines such as fluvoxamine, used for the treatment of obsessive-compulsive disorder may increase the levels of PANTOCID OTC in your body. An antibiotic medicine called rifampicin and St John's wort (*Hypericum perforatum* an herbal supplement / natural medicine used to treat mild depression) may reduce the effect of PANTOCID OTC.

Tell your doctor, pharmacist or other health care provider if you are currently using:

- Ketoconazole, Itraconazole, Posaconazole or Voriconazole (used to treat fungal infections).
- Erlotinib (used to treat cancer).
- PANTOCID OTC must not be used together with HIV protease inhibitor medicines such as Atazanavir or Nelfinavir (used to treat HIV infection).
- Warfarin (used to prevent blood clots from forming). Your doctor may need to monitor your blood.
- Methotrexate (used to treat rheumatoid arthritis, psoriasis, and cancer). If you are taking methotrexate, your doctor may temporarily stop your PANTOCID OTC treatment.

PANTOCID OTC with food, drink and alcohol

Speak to your doctor or pharmacist before taking PANTOCID OTC if you are taking alcohol or St John's wort on a regular basis.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking PANTOCID OTC.

Do not take PANTOCID OTC if you are pregnant or breastfeeding your baby.

Driving and using machines

PANTOCID OTC can cause side effects, such as dizziness and blurred vision. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how PANTOCID OTC affects you.

PANTOCID OTC contains lactose and mannitol

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking PANTOCID OTC.

3. How to take PANTOCID OTC

Do not share medicines with any other person.

Always take PANTOCID OTC exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one 20 mg PANTOCID OTC tablet per day for up to 14 days when need.

You must consult a doctor if your symptoms worsen or do not improve after 14 days.

Elderly people and those with reduced liver or kidney function do not require any dosage adjustments.

The once daily dose of PANTOCID OTC should be taken in the morning. The tablet should be swallowed whole with a little water either before or during breakfast. Do not crush, break or chew the tablet.

If you have the impression that the effect of PANTOCID OTC is too strong or too weak, tell your doctor or pharmacist.

If you take more PANTOCID OTC than you should

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

Take this leaflet and the remaining PANTOCID OTC with you so the doctor will know what you have taken.

If you forget to take PANTOCID OTC

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

PANTOCID OTC can have side effects.

Not all side effects reported for PANTOCID OTC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PANTOCID OTC, please consult your health care provider for advice.

If any of the following happens, stop taking PANTOCID OTC and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing

- rash or itching
- fainting

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to PANTOCID OTC. 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:

- painful, blistering or peeling skin rash, such as Stevens-Johnson syndrome or Lyell syndrome
- yellowing of skin or eyes, itching, stomach pain, dark urine or rash (symptoms of liver damage that could lead to liver failure)
- passing more or less urine than is normal for you, blood in your urine, dark urine, nausea (feeling sick), vomiting (being sick)
- persistent watery diarrhoea, stomach pain and fever
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal

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

Tell your doctor if you notice any of the following:

Side effects occurring frequently:

- headache
- benign polyps in the stomach, stomach pain, diarrhoea, constipation and bloating

Side effects occurring less frequently:

- increase of fat levels in the blood
- changes in weight
- sleep disorders
- feeling depressed, disorientated or confused

- dizziness
- changes in taste
- blurred vision
- nausea (feeling sick), vomiting (being sick) or dry mouth
- changes in liver enzymes when testing your liver function
- increase in bilirubin (formed when red blood cells break down)
- increased sensitivity to sunlight
- Increased risk of hip, wrist or spin fractures
- pain in a joint, pain in a muscle or group of muscles, muscle spasm
- abnormal physical weakness or lack of energy, feeling tired, generally feeling unwell
- increase in body temperature
- swollen ankles, hands and feet

Side effects occurring with an unknown frequency:

- decreased levels of sodium, magnesium, calcium and potassium in the blood
- seeing, hearing or sensing things that are not real
- tingling or numbness of your hands and feet (pins and needles)
- breast enlargement in men

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 healthcare professional. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of PANTOCID OTC.

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5. How to store PANTOCID OTC

- Store at or below 25 °C.
- Protect from light and moisture.
- Keep the blister strips in the outer carton until required for use.
- Keep the tablets in the original HDPE container until required for use and keep the container tightly closed.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the container/carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PANTOCID OTC contains

The active substance is pantoprazole. Each tablet contains pantoprazole sodium sesquihydrate equivalent to 20 mg pantoprazole.

The other ingredients are mannitol, sodium carbonate anhydrous, lactose anhydrous, crospovidone, povidone, calcium stearate, Hypromellose, polyethylene glycol, talc, methacrylic acid copolymer type C, triethyl citrate, titanium dioxide (E171) and iron oxide yellow (E172).

What PANTOCID OTC looks like and contents of the pack

Yellow, circular, biconvex, coated tablet, plain on both sides.

OPA/PVC/Aluminium foil blister strips placed in an outer carton.

Ranbaxy Pharmaceuticals (Pty) Ltd
PANTOCID OTC

Gastro-resistant tablets
20 mg Pantoprazole per tablet

White, round HDPE containers with a white, ribbed polypropylene child-resistant cap.

Pack size: 7, 10 or 14 tablets.

Not all pack sizes may be marketed simultaneously.

Holder of certificate of registration

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