

Applicant: Mylan (Pty) Ltd
Proprietary Name: Prazgen OTC
Dosage form: 20 mg Modified release tablet
Each tablet contains 20 mg pantoprazole

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S2

PRAZGEN OTC 20 mg Modified release tablet

Pantoprazole

Contains mannitol

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

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

Nevertheless, you still need to use PRAZGEN OTC carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share PRAZGEN OTC with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7-14 days.

What is in this leaflet

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

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

PRAZGEN OTC contains the active substance pantoprazole.

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

PRAZGEN OTC is indicated for:

- The temporary short-term relief of heartburn and hyperacidity for a maximum daily dose of 20 mg and a maximum treatment period of 14 days.

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

Do not take PRAZGEN OTC:

- if you are allergic (hypersensitive) to pantoprazole or any other ingredients of PRAZGEN OTC (listed in section 6).
- if your liver function is impaired.
- PRAZGEN OTC 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 PRAZGEN OTC:

- 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.
- If you have a history of a Vitamin B12 deficiency.
- If you develop diarrhoea that does not improve, contact your doctor or healthcare professional as soon as possible.
- If you are over 50 years of age or when you take PRAZGEN OTC 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 have or had a bone fracture in the hip, wrist or spine due to low magnesium.

Special patient groups

- If you suffer from **severe liver problems**, you should not take PRAZGEN OTC.
- **Children below 12 years.** These tablets are not recommended for use in children below 12 years.

Other medicines and PRAZGEN OTC

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

It is especially important to tell you doctor if you are taking the following medicines:

- Medicines such as **ketoconazole**, **itraconazole** and **posaconazole** (used to treat fungal infections) or **erlotinib** (used for certain types of cancer) because PRAZGEN tablets may stop these and other medicines from working properly.
- **Warfarin** which affect the thickening or thinning of the blood. You may need further checks.
- **Methotrexate** (used in treatment of cancer and autoimmune diseases)
- **Atazanavir** (used to treat HIV-infection).

PRAZGEN OTC with food and drink:

PRAZGEN OTC should be taken before a meal, preferably in the morning.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby while taking PRAZGEN OTC, please consult

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your doctor, pharmacist or other healthcare professional for advice before taking PRAZGEN OTC.

You should not take PRAZGEN OTC if you are pregnant or breastfeeding your baby.

Driving and using machines

PRAZGEN OTC may cause blurred vision or dizziness. You should refrain from driving or using machinery until you know how PRAZGEN OTC affects you.

Important information about some of the ingredients of PRAZGEN OTC:

PRAZGEN OTC tablets contain mannitol and may have a laxative effect.

3. How to take PRAZGEN OTC

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

The tablets should be swallowed whole. Do not crush, break or chew the tablet.

It may take several days before PRAZGEN OTC begins to relieve your symptoms. To help relieve your symptoms, antacids may be taken with PRAZGEN OTC, unless your doctor has told you not to use them.

If you take more PRAZGEN OTC 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 you have taken.

If you forgot to take or missed a dose of PRAZGEN OTC:

If you miss a dose of PRAZGEN OTC, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule.

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

4. Possible side effects

PRAZGEN OTC can have side effects.

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

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

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

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

- stomach pain (severe),
- blistering, loosening, peeling or redness of skin,
- 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:

- benign polyps in the stomach (nausea, tenderness or pain).

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Less frequent side effects:

- headache,
- dizziness;
- diarrhoea;
- feeling sick, vomiting;
- bloating and flatulence (wind);
- constipation; dry mouth;
- abdominal pain and discomfort;
- skin rash, exanthema, eruption;
- itching; feeling weak, exhausted or generally unwell;
- sleep disorders; fracture of the hip, wrist or spine;
- disturbances in vision such as blurred vision;
- hives; pain in the joints;
- muscle pains;
- weight changes;
- raised body temperature;
- swelling of the extremities (peripheral oedema);
- allergic reactions;
- depression;
- breast enlargement in males;
- agranulocytosis (severe reduction in number of white blood cells, which makes infections more likely), taste disorders;
- disorientation, thrombocytopenia (reduction in blood platelets, which increases risk of bleeding or bruising), leukopenia (decrease in the number of white blood cells (leukocytes), pancytopenia (severe reduction in blood cells which can cause weakness, bruising or make infections more likely).

Frequency unknown:

- pins and needles / tingling, inflammation in the large bowel, that causes persistent watery diarrhoea, hallucination, confusion (especially in patients with a history of these symptoms);
- decreased sodium level, decreased calcium level, decreased potassium level in blood.

If you are on PRAZGEN OTC 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.

- Rash, possibly with pain in the joints.

Side effects identified through blood tests:

Less frequent:

- an increase in liver enzymes,
- an increase in bilirubin; increased fats in the blood,
- a reduction in the number of blood platelets, which may cause you to bleed or bruise more than normal; a reduction in the number of white blood cells, which may lead to more frequent infections.

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

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Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse.

You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:
<https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of PRAZGEN OTC.

5. How to store PRAZGEN OTC

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from light.

Keep the blisters in the carton until required for use.

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

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What PRAZGEN OTC contains

The active ingredient is pantoprazole.

Each PRAZGEN OTC tablet contains:

Pantoprazole sodium sesquihydrate equivalent to 20 mg pantoprazole.

Contains sugar: mannitol.

The other ingredients are:

Tablet core:

Sodium carbonate anhydrous

Mannitol

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Crospovidone

Povidone

Calcium stearate

Methacrylic acid- ethyl acrylate copolymer (1:1) dispersion 30 %

Triethyl citrate

Tablet coating:

Opadry Yellow IH (OY-52945), containing:

Hypromellose

Titanium dioxide

Macrogol

Iron oxide yellow

Imprinting:

Opacode black IH (S-1-17823), containing:

Shellac

Isopropyl alcohol

Ferrosoferric oxide

N-Butyl alcohol

Propylene glycol

Ammonium hydroxide 28 %

What PRAZGEN OTC looks like and contents of the pack

A dark yellow, film-coated, oval, approximately 4,3 mm X 8,4 mm, biconvex tablet that is blank on both sides.

Contents of the pack:

Blister pack of form laminate with desiccant layer on one side with a back of hard-

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tempered aluminium foil (dull side lacquered and bright side PE extrusion side).

Blister of aluminium foil laminated to polyamide on one side & laminated PVC on the other side and hard tempered aluminium foil coated with heat seal laquer.

Pack sizes: 7 or 14 tablets are packed in a cardboard carton.

Holder of Certificate of Registration

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