

**DR REDDY'S LABORATORIES (PTY) LTD.
PENTOZ OTC
APPROVED PATIENT INFORMATION LEAFLET
27.01.2021**

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

PENTOZ OTC, delayed release film-coated tablet

Pantoprazole sodium sesquihydrate

Contains sugar (mannitol)

Each film-coated tablet contains 38,95 mg of mannitol.

Read all of this leaflet carefully before you start taking PENTOZ OTC

PENTOZ OTC film-coated tablets are available without a doctor's prescription for you to treat a mild illness.

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- Do not share PENTOZ OTC with any other person.
- You must see a doctor if your symptoms worsen or do not improve after 14 days.

What is in this leaflet:

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

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

PENTOZ OTC is used in adults for the temporary short-term relief of heartburn and to treat conditions where the stomach produces too much acid (hyperacidity).

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

Do not take PENTOZ OTC:

- if you are hypersensitive (allergic) to pantoprazole or any of the other ingredients of PENTOZ OTC (see list under Section 6);
- if you are pregnant or breastfeeding your baby (see Section 2, Pregnancy and Breastfeeding);
- if you have a serious liver problem;
- if you are taking medicines for HIV known as atazanavir or nelfinavir (antiretrovirals). These medicines may not work as well against your HIV infection if you take them with PENTOZ OTC.

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

Warnings and precautions

Take special care with PENTOZ OTC

You must contact your medical doctor 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;
- feel very tired.

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

- PENTOZ OTC increases the risk of bacterial infections of the digestive tract. Contact your doctor for advice as soon as possible if you experience symptoms such as persistent loose or watery stools, especially if combined with nausea, vomiting, stomach cramps and/or

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fever.

- PENTOZ OTC can cause a type of kidney problem (acute tubulointerstitial nephritis). Some people who take proton pump inhibitor (PPI) medicines, including PENTOZ OTC, may develop a kidney problem called acute tubulointerstitial nephritis that can happen at any time during treatment with PENTOZ OTC. Call your doctor right away if you have a decrease in the amount that you urinate or if you have blood in your urine.

Contact your doctor or speak to your pharmacist before taking PENTOZ OTC if:

- you have or ever had liver problems or jaundice.
- you have severe kidney problems.
- you have osteoporosis.
- you have been taking continuously, for 4 weeks or longer, medication for heartburn and/or indigestion.

Since PENTOZ OTC may cause you to be more sensitive to sunburn, you should take precautions when exposed to sunlight.

You should not use PENTOZ OTC for mild complaints such as indigestion caused by stress or emotional upsets. Speak to your doctor or pharmacist.

Other medicines with PENTOZ OTC

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines).

If you are taking any medicine, and in particular any of the following medicines, consult your doctor or pharmacist before taking PENTOZ OTC tablets.

- Antiretroviral medicines known as atazanavir and nelfinavir. (See Section 2).
- If you are taking a medicine known as voriconazole.
- Warfarin:

If you are taking warfarin to prevent clots, your blood may become too thin if you take it with PENTOZ OTC. Your risk of bleeding may increase. Speak to your doctor as you may need

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additional tests to check your blood (INR tests).

- Certain medicines may not be absorbed well if taken with PENTOZ OTC and may therefore be less effective e.g.
 - ketoconazole, itraconazole and posaconazole used for fungal disease. Thrush and athlete's foot are examples of fungal diseases;
 - ampicillin (antibiotics used for infections);
 - iron supplements.

If you are taking digoxin for heart problems, PENTOZ OTC may result in increased levels of digoxin in your blood with worsening of its unwanted effects.

- diazepam (to calm you), and/or phenytoin (for epilepsy) as your doses may have to be decreased;
- high doses of methotrexate e.g. 300 mg daily (sometimes given for psoriasis, a skin disease marked by red, itchy, scaly patches or for rheumatoid arthritis, a chronic progressive disease causing inflammation in the joints).

PENTOZ OTC with food and drink

PENTOZ OTC can be taken with or without food.

Speak to your doctor or pharmacist before taking PENTOZ OTC if you are taking alcohol on a regular basis.

Pregnancy and Breastfeeding

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

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 receiving this medicine.

Driving and using machines

PENTOZ OTC may make you feel dizzy or make you see less clearly.

Do not drive vehicles or operate any hazardous tools or machines unless you are sure that PENTOZ OTC will not stop you from doing so safely.

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PENTOZ OTC contains mannitol

PENTOZ OTC contains mannitol which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using PENTOZ OTC.

3. How to take PENTOZ OTC

Always take PENTOZ OTC exactly as instructed below. You should check with your doctor or pharmacist if you are unsure.

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

PENTOZ OTC is for adults only.

- Take one PENTOZ OTC tablet per day, before or during breakfast.
- PENTOZ OTC should be swallowed whole with about a quarter glass of water.
- Do not break or crush the tablet.
- Do not chew the tablet.
- The maximum dose is one tablet per day for a maximum period of 14 days.
- If your symptoms have not gone away after 14 days of continuous treatment, consult your doctor.
- You should not take more than three 14-day courses of PENTOZ OTC in a 12-month period without consulting your doctor.
- The use of PENTOZ OTC for longer than 14 days, or more often than three times in a 12-month period is not advised unless you are under the supervision of your doctor.

If you take more PENTOZ OTC than you should

If you have taken more PENTOZ OTC tablets than you should, consult your doctor or pharmacist.

If neither is available, seek help at the nearest hospital or poison control centre.

There is limited information available on the effects of very high doses.

If you forget to take PENTOZ OTC

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Take the missed dose as soon as you remember. If, however, it is almost time for your next dose, do not take a double dose to make up for the missed dose. Continue with the normal dose of one tablet per day before or during breakfast.

If you stop taking PENTOZ

Do not stop taking PENTOZ unless your doctor tells you to.

4. Possible side effects

PENTOZ OTC can have side effects.

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

Some less frequent side effects of PENTOZ OTC can be serious. If any of the following happen to you, stop taking PENTOZ OTC and tell your doctor immediately or go to the casualty department at your nearest hospital as you will need immediate medical attention or hospitalisation:

- If you have an allergic reaction to PENTOZ OTC with effects such as swelling of the mouth, tongue or face and/or throat, difficulty to breathe or swallow, red lumpy skin rash (hives), dizziness (which may be as a result of a sudden fall in blood pressure leading to collapse or shock).
- If you experience itching, right upper-belly pain, dark urine, yellow skin/eyes (jaundice), and unexplained flu-like symptoms.
- If you develop severe flu-like symptoms followed by severe skin blisters with redness around them, or a peeling rash, hives and/or mouth sores: These are symptoms of Stevens-Johnson syndrome, a sometimes fatal form of allergic skin disease.
- Problems with passing urine or if you pass urine more often than usual and develop a fever and generally feel unwell, or if you notice blood in your urine.
- Watery stool/runny tummy that does not go away, accompanied by stomach pain and fever; these are the symptoms of infection requiring medical treatment (See Section 2).

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The most frequent side effects of PENTOZ OTC are:

digestive tract problems such as stomach pain, runny tummy (watery stools), constipation and bloating (gas) and headache .

Other less frequent effects include:

- nausea (feeling sick),
- vomiting,
- dry mouth,
- feeling abnormally weak and tired,
- generally feeling unwell,
- swollen hands and feet,
- hypersensitivity (allergic reactions) (see above),
- not seeing clearly,
- blood test results showing
 - impaired liver function,
 - increase of certain fats in the blood (triglycerides, cholesterol),-increase in bilirubin (formed when red blood cells breakdown), weight changes,
- increase in body temperature,
- joint pain,
- muscle pain,
- increased risk of wrist, hip and spine bone breaks,
- feeling of dizziness or feeling like 'spinning',
- taste disorders,
- feeling down,
- not sleeping well,
- feeling confused or baffled,
- inflammation of the small, narrow spaces in the tissue of the kidney that can cause kidney problems,
- decrease in the blood of the number of
 - red cells, white cells, and platelets (pancytopenia),

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- white blood cells (leukopenia) (may increase the risk of inflammation/infection),
- platelets (thrombocytopenia) (may increase risk of bruising or bleeding),
- sharp drop in circulating granular white blood cells (agranulocytosis) - an acute disease marked by high fever.

- oversensitivity to sunlight.

Side effects of unknown frequency:

- runny tummy due to bacterial infections,
- severe liver damage that can lead to liver failure (see Section 2).
- enlarged breasts in men,
- decrease in magnesium sodium in the blood,
- feeling or experiencing things that seem real, but that do not in fact really happen (hallucinations).

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

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions 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 PENTOZ OTC.

5. How to store PENTOZ OTC

Keep out of the reach and sight of children.

Store at or below 25 °C and protect from light and moisture.

Do not store in bathrooms.

Keep the tablets in the original blisters and keep the blisters in the carton until required for use.

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Keep the tablets in the plastic container until required for use and keep the container tightly closed.

Do not use after the expiry date stated on the containers/labels.

Do not use PENTOZ OTC if the tablets have any visible signs of deterioration such as discolouration or chipping.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

The active substance is pantoprazole.

Each PENTOZ OTC film-coated tablet contains pantoprazole sodium sesquihydrate equivalent to pantoprazole 20 mg.

The other ingredients of the tablets are calcium stearate, crospovidone, hydroxypropyl cellulose, methacrylic acid/ethyl acrylate copolymer, sodium carbonate anhydrous, talc, titanium dioxide, triethyl citrate and zein.

The film-coating contains hydroxypropyl methyl cellulose, polyethylene glycol (macrogol), synthetic yellow iron oxide and titanium dioxide.

The printing ink (black) contains ammonium hydroxide (trace amounts), iron oxide black and shellac.

What PENTOZ OTC looks like and contents of the pack

Yellow, round, biconvex film-coated tablets printed with "P20" on one side with black ink and plain on the other side.

7, 10 or 14 film-coated tablets are packed in white HDPE containers or in aluminium/aluminium blister strips, packed into outer cartons.

Holder of Certificate of Registration

Dr. Reddy's Laboratories (Pty) Ltd.

Block B, 204 Rivonia Road

Morningside

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Registration number

45/11.4.3/0592

For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration:

Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100

Access to the corresponding Professional Information

Detailed information on this medicine is available on the Dr.

Reddy's Laboratories (Pty) Ltd. website: <http://www.drreddys.co.za>