

PATIENT INFORMATION LEAFLET: PANFLUX OTC

SCHEDULING STATUS:

S2

PANFLUX OTC 20 mg gastro-resistant tablets

Pantoprazole sodium sesquihydrate

Contains sugar: maltitol 38,425 mg/tablet

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

PANFLUX OTC is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use PANFLUX OTC carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share PANFLUX OTC with any other person.
- Ask your healthcare 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 PANFLUX OTC is and what it is used for
2. What you need to know before you take PANFLUX OTC
3. How to take PANFLUX OTC
4. Possible side effects
5. How to store PANFLUX OTC
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1. What PANFLUX OTC is and what it is used for

PANFLUX 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 PANFLUX OTC

Do not take PANFLUX OTC:

- If you are hypersensitive (allergic) to pantoprazole or any of the other ingredients of PANFLUX OTC (listed in 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 PANFLUX OTC.

PANFLUX 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 PANFLUX 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.

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

PANFLUX 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 fever.

PANFLUX OTC can cause a type of kidney problem (acute tubulointerstitial nephritis). Some people who take proton pump inhibitor (PPI) medicines, including PANFLUX OTC, may develop a kidney problem called acute tubulointerstitial nephritis that can happen at any time during treatment with PANFLUX 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 PANFLUX 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 PANFLUX OTC may cause you to be more sensitive to sunburn, you should take precautions when exposed to sunlight.

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

If you use PANFLUX OTC for a long period of time, you may experience falling magnesium levels in your blood (potential symptoms: fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate). Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. You should talk to your doctor if you have been using this product for a long period of time. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

Other medicines with PANFLUX OTC

Always tell your healthcare professional if you are taking any other medicine. (This includes all 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 PANFLUX 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 PANFLUX OTC. Your risk of bleeding may increase. Speak to your doctor as you may need additional tests to check your blood (INR tests).

- Certain medicines may not be absorbed well if taken with PANFLUX 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, PANFLUX 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).

PANFLUX OTC with food and drink

PANFLUX OTC can be taken with or without food.

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

Pregnancy and breastfeeding

Do not take PANFLUX 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 healthcare provider for advice before taking this medicine.

Driving and using machines

PANFLUX 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 PANFLUX OTC will not stop you from doing so safely.

PANFLUX OTC contains maltitol

PANFLUX OTC contains maltitol 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 taking PANFLUX OTC.

PANFLUX OTC contains sodium

PANFLUX OTC contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take PANFLUX OTC

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

Always take PANFLUX OTC exactly as described in this leaflet or as your doctor, or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

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

PANFLUX OTC is for adults only.

Take one PANFLUX OTC tablet per day, before or during breakfast.

PANFLUX 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 PANFLUX OTC in a 12-month period without consulting your doctor.

The use of PANFLUX 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 PANFLUX OTC than you should

If you have taken more PANFLUX OTC tablets than you should, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison centre.

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

If you forget to take PANFLUX OTC

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 PANFLUX OTC

Do not stop taking PANFLUX OTC unless your doctor tells you to.

4. Possible side effects

PANFLUX OTC can have side effects.

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

Some less frequent side effects of PANFLUX OTC can be serious. If any of the following happen to you, stop taking PANFLUX 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 PANFLUX 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).

The most frequent side effects of PANFLUX 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);
 - 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;
- decreased levels of sodium, magnesium, calcium or potassium in 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. If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafety@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of PANFLUX OTC.

5. How to store PANFLUX OTC

Store at or below 25 °C in a cool, dry place.

Keep the bottles tightly closed and store in the original packaging to protect from light and moisture.

Store the blisters in the outer carton in order to protect from light and moisture.

Store all medicines out of reach of children.

Do not refrigerate or freeze.

Do not use after the expiry date stated on the blisters or bottle and/or carton.

For bottles: Do not use after 3 months from first opening.

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 PANFLUX OTC contains

The active substance is pantoprazole.

Each gastro-resistant tablet contains pantoprazole sodium sesquihydrate equivalent to 20 mg pantoprazole.

The other ingredients are (tablet core): calcium stearate, carmellose sodium, crospovidone, maltitol, sodium carbonate anhydrous, (tablet coat): lecithin, macrogol 3350, methacrylic acid – ethyl acrylate copolymer (1:1),

polyvinyl alcohol, sodium carbonate anhydrous, talc, titanium dioxide (E171), triethyl citrate, yellow iron oxide (E172).

What PANFLUX OTC looks like and contents of the pack

Gastro-resistant tablets.

Yellow coloured, oval (8,2 mm x 4,4 mm) shaped, gastro-resistant tablets.

Pack size: Aluminium/Aluminium blister packs and/or PVC/PE/PVdC–Aluminium blister packs and/or HDPE bottles of 14 tablets.

Blister packs are contained in an outer cardboard carton.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

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