

Package leaflet: Information for the user

Freestom 20 mg gastro-resistant tablets

Pantoprazole

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

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

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 weeks.

What is in this leaflet

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

1. What **Freestom is and what it is used for**

Freestom contains the active substance pantoprazole, which blocks the “pump” that produces stomach acid. Hence it reduces the amount of acid in your stomach.

Freestom is used for the short-term treatment of reflux symptoms (for example heartburn, acid regurgitation) in adults.

Reflux is the backflow of acid from the stomach into the gullet (“foodpipe”), which may become inflamed and painful. This may cause you symptoms such as a painful burning sensation in the chest rising up to the throat (heartburn) and a sour taste in the mouth (acid regurgitation).

You may experience relief from your acid reflux and heartburn symptoms after just one day of treatment with **Freestom**, but this medicine is not meant to bring immediate relief. It may be necessary to take the tablets for 2-3 consecutive days to relieve the symptoms.

2. What you need to know before you take **Freestom**

Do not take **Freestom**

- if you are allergic to pantoprazole, soya lecithin or any of the other ingredients of this medicine (listed in section 6).
- if you are taking a medicine containing atazanavir (for the treatment of HIV-infection), See ‘Other medicines and **Freestom**’.

Warnings and precautions

Talk to your doctor or pharmacist before taking **Freestom**

- if you have liver problems or jaundice (yellowing of skin or eyes).
- if you have been treated for heartburn or indigestion continuously for 4 or more weeks.
- if you are over 55 years old and taking non-prescription indigestion treatment on a daily basis.
- if you are over 55 years old with any new or recently changed reflux symptoms.
- if you have previously had a gastric ulcer or stomach surgery.
- if you regularly see your doctor for serious complaints or conditions.
- if you are due to have an endoscopy or a breath test called a C-urea test.

Tell your doctor immediately, before or after taking this medicine, if you notice any of the following symptoms, which could be a sign of another, more serious, disease:

- an unintentional loss of weight (not related to a diet or an exercise programme).
- vomiting, particularly if repeated.
- vomiting blood; this may appear as dark coffee grounds in your vomit.
- you notice blood in your stools; which may be black or tarry in appearance.
- difficulty in swallowing or pain when swallowing.
- you look pale and feel weak (anaemia).
- chest pain.
- stomach pain.
- severe and/or persistent diarrhoea, because **Freestom** has been associated with a small increase in infectious diarrhoea.

Your doctor may decide that you need some tests.

If you are due to have a blood test, tell your doctor that you are taking this medicine.

You may experience relief from your acid reflux and heartburn symptoms after just one day of treatment with **Freestom**, but this medicine is not meant to bring immediate relief. You should not take it as a preventive measure.

If you have been suffering from repetitive heartburn or indigestion symptoms for some time, remember to see your doctor regularly.

Children and adolescents

Freestom should not be used by children and adolescents under 18 years of age due to a lack of safety information in this younger age group.

Other medicines and Freestom

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Freestom may stop certain other medicines from working properly. Tell your doctor or pharmacist if you are using any medicines containing one of the following active substances:

- atazanavir (used to treat HIV-infection). You must not use Freestom if you are taking atazanavir. See ‘Do not take Freestom’.
- ketoconazole (used for fungal infections).
- warfarin and phenprocoumon (used to thin blood and prevent clots). You may need further blood tests.
- methotrexate (used to treat rheumatoid arthritis, psoriasis, and cancer) – if you are taking methotrexate your doctor may temporarily stop your Freestom treatment because pantoprazole can increase levels of methotrexate in the blood.

Do not take Freestom with other medicines which limit the amount of acid produced in your stomach, such as another proton pump inhibitor (omeprazole, lansoprazole or rabeprazole) or an H₂-antagonist (e.g. ranitidine, famotidine).

However, you may take Freestom with antacids (e.g. magaldrate, alginic acid, sodium bicarbonate, aluminium hydroxide, magnesium carbonate, or combinations thereof), if needed.

Pregnancy and breast-feeding

You should not take this medicine if you are pregnant or while-breastfeeding. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

If you experience side effects like dizziness or disturbed vision, you should not drive or operate machines.

Freestom contains maltitol and lecithin

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Freestom contains soya lecithin. If you are allergic to peanut or soya, do not use this medicine.

3. How to take Freestom

Always take this medicine 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.

Take one tablet a day. Do not exceed this recommended dose of 20 mg pantoprazole daily.

You should take this medicine for at least 2 – 3 consecutive days. Stop taking **Freestom** when you are completely symptom-free. You may experience relief from your acid reflux and heartburn symptoms after just one day of treatment with **Freestom**, but this medicine is not meant to bring immediate relief.

If you have no symptom-relief after taking this medicine for 2 weeks continuously, consult your doctor. Do not take **Freestom** tablets for more than 4 weeks without consulting your doctor.

Take the tablet before a meal, at the same time every day. You should swallow the tablet whole with some water. Do not chew or break the tablet.

If you take more **Freestom than you should**

Tell your doctor or pharmacist if you have taken more than the recommended dose. If possible take your medicine and this leaflet with you.

If you forget to take **Freestom**

Do not take a double dose to make up for the forgotten dose. Take your next, normal dose, the next day, at your usual time.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately or contact the casualty department at your nearest hospital, if you get any of the following **serious side effects**. Stop taking this medicine straight away, but take this leaflet and/or the tablets with you.

- **Serious allergic reactions (frequency rare:** may affect up to 1 in 1,000 people): Hypersensitivity reactions, so-called anaphylactic, reactions anaphylactic shock and angioedema. Typical symptoms are: swelling of the face, lips, mouth, tongue and/or throat, which may cause difficulty in swallowing or breathing, hives (nettle rash), severe dizziness with very fast heartbeat and heavy sweating.
- **Serious skin reactions (frequency not known:** frequency cannot be estimated from the available data): rash with swelling, blistering or peeling of the skin, losing skin and bleeding around eyes, nose, mouth or genitals and rapid deterioration of your general health, or rash when exposed to the sun.
- **Other serious reactions (frequency not known:** frequency cannot be estimated from the available data): yellowing of the skin and eyes (due to severe liver damage), or kidney problems such as painful urination and lower back pain with fever.

In the course of the treatment with active substance of the product **Freestom** following adverse effects have been observed:

- **Uncommon** (may affect up to 1 in 100 people)
Headache; dizziness; diarrhoea; feeling sick, vomiting; bloating and flatulence (wind); constipation; dry mouth; bellyache and discomfort; skin rash or hives; itching; feeling weak exhausted or generally unwell; sleep disorders; increase in liver enzymes in a blood test
- **Rare** (may affect up to 1 in 1,000 people)
Distortion or complete lack of the sense of taste; disturbances in vision such as blurred vision; pain in the joints; muscle pains; weight changes; raised body temperature; swelling of the extremities; depression; increased bilirubin and fat levels in blood (seen in blood tests), breast enlargement in males; high fever and a sharp drop in circulating granular white blood cells (seen in blood tests).
- **Very rare** (may affect up to 1 in 10,000 people)
Disorientation; reduction in the number of blood platelets, which may cause you to bleed or bruise more than normal; reduction in the number of white blood cells, which may lead to more frequent infections, coexisting abnormal reduction in the number of red and white blood cells, as well as platelets (seen in blood tests).
- **Not known** (frequency cannot be estimated from the available data)
Hallucination, confusion (especially in patients with a history of these symptoms); decreased level of sodium in blood, decreased level of magnesium in blood.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store **Freestom**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the blister or bottle and carton. The expiry date refers to the last day of that month.

For tablets packed in plastic bottles: **Freestom** must be used within three months after first opening of the container.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Freestom contains

- The active substance is pantoprazole. Each tablet contains 20 mg pantoprazole (as sodium sesquihydrate).
- The other ingredients are:
Tablet core: Maltitol (E 965), crospovidone type B, carmellose sodium, sodium carbonate anhydrous, calcium stearate.
Tablet coating: Poly(vinyl alcohol), talc, titanium dioxide (E 171), macrogol 3350, soya lecithin, iron oxide yellow (E 172), sodium carbonate anhydrous, methacrylic acid-ethyl acrylate copolymer (1:1), sodium laurilsulfate, polysorbate 80, triethyl citrate.

What Freestom looks like and contents of the pack

The gastro-resistant tablets are oval, yellow, gastro-resistant tablets.

Freestom is available in oPA/Alu/PVC-Aluminium blisters or HDPE bottles.

Packs containing 7 or 14 gastro-resistant tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

sanofi-aventis Ireland Limited
Citywest Business Campus
Dublin 24
Ireland

Manufacturer

SANOFI-AVENTIS Sp.z.o.o
ul. Bonifraterska 17
00-203 Warsaw
Poland

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: Ipraalox 20 mg - magensaftresistente Tabletten
Belgium: Maalox Control 20 mg comprimés gastro-résistants
Czech Republic: Maalostar 20 mg enterosolventní tableta
Estonia: Ipraalox
Greece: Ipraalox 20 mg Γαστροανθεκτικό δισκίο
France: Ipraalox 20 mg comprimés gastro-résistants
Ireland: Freestom 20 mg gastro-resistant tablets
Italy: Maalox Reflusso 20 mg compresse gastroresistenti
Lithuania: Ipraalox 20 mg skrandyje neirios tabletės
Latvia: Ipraalox 20 mg zarnās šķīstošās tabletes
The Netherlands: Ipraalox, 20 mg maagsapresistente tabletten

Pantoprazol NL/H//1849 - Update according to CSP

Portugal: Stomafor

Romania: Dicarbocalm Control 20 mg comprimate gastrorezistente

Slovenia: Ipraalox 20 mg gastrorezistentne tablete

Slovak Republic: Ipraalox 20 mg gastrorezistentné tablety

This leaflet was last revised in {09/2014}.

The following recommendations for lifestyle and dietary changes may also help to relieve heartburn or acid related symptoms.

- Avoid large meals.
- Eat slowly.
- Stop smoking.
- Reduce alcohol and caffeine consumption.
- Reduce weight (if overweight).
- Avoid tight-fitting clothing or belts.
- Avoid eating less than three hours before bedtime.
- Elevate bedhead (if you suffer from nocturnal symptoms).
- Reduce intake of food that can cause heartburn. These might include: Chocolate, peppermint, spearmint, fatty and fried food, acidic food, spicy food, citrus fruits and fruit juices, tomatoes.