Package leaflet: Information for the patient

Lansoprazol Viatris 15 mg Orodispersible Tablets
Lansoprazol Viatris 30 mg Orodispersible Tablets

lansoprazole

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet

1. What <INVENTED NAME> is and what it is used for

The active ingredient in <INVENTED NAME> is lansoprazole, which is a proton pump inhibitor. Proton pump inhibitors reduce the amount of acid that your stomach makes.

Your doctor may prescribe <INVENTED NAME> for the following:
- Treatment of duodenal (gut) and stomach ulcers.
- Treatment of inflammation in your food pipe (reflux oesophagitis).
- Prevention of reflux oesophagitis.
- Treatment of heartburn and acid regurgitation.
- Treatment of infections caused by the bacteria *Helicobacter pylori* when given together with an antibiotic.
- Treatment or prevention of duodenal (gut) or stomach ulcer in patients requiring continued non-steroidal anti-inflammatory drugs (NSAID) treatment (NSAID treatment is used against pain or inflammation).
- Treatment of Zollinger-Ellison syndrome.

Your doctor may have prescribed <INVENTED NAME> to treat another condition or with a dose different from those written in this leaflet. Please follow your doctor's instructions for taking your medicine.

2. What you need to know before you take <INVENTED NAME>

Do not take <INVENTED NAME>:

- if you are allergic to lansoprazole or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking <INVENTED NAME>:

- if you have liver problems. The doctor may have to adjust your dose.
- if you have ever had a skin reaction after treatment with a medicine similar to lansoprazole that reduces stomach acid.
- if you are due to have a specific blood test (Chromogranin A).
- if you have low vitamin B_{12} levels or have risk factors for low vitamin B_{12} levels and receive long-term treatment with this medicines. As with all acid reducing agents, <INVENTED NAME> may lead to a reduced absorption of vitamin B_{12}.

This medicine may affect the way that your body absorbs vitamin B_{12}, particularly if you need to take it for a long time. Please contact your doctor if you notice any of the following symptoms, which could indicate low levels of Vitamin B_{12}:

- Extreme tiredness or lack of energy
- Pins and needles
- Sore or red tongue, mouth ulcers
- Muscle weakness
- Disturbed vision
- Problems with memory, confusion, depression

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with lansoprazole treatment. Stop using <INVENTED NAME> and seek medical attention immediately if you notice any of the symptoms described in section 4.

If you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with lansoprazole. Remember to also mention any other ill-effects like pain in your joints.

If your doctor has given you <INVENTED NAME> in addition to other medicines intended to treat infection caused by the bacteria *Helicobacter pylori* (antibiotics) or together with anti-inflammatory medicines to treat your pain or rheumatic disease, please also read the package leaflets of these medicines carefully.

Your doctor may perform or have performed an additional investigation called an endoscopy in order to diagnose your condition and/or exclude malignant disease.

When taking <INVENTED NAME>, inflammation in your kidney may occur. Signs and symptoms may include decreased volume of urine or blood in your urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness. You should report such signs to the treating physician.

If you take <INVENTED NAME> for more than three months your magnesium levels in your blood may become very low. If you get very tired, disorientated, dizzy or have muscle twitches, convulsions (fits) or an increased heart rate, contact your doctor immediately as you may have low levels of magnesium in the blood (see section 4 ‘Possible side effects’). A decrease of magnesium levels in your blood may also lead to a decrease of calcium and potassium levels in your blood. Therefore, your doctor may monitor the magnesium levels in your blood.

Taking a proton pump inhibitor like <INVENTED NAME>, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

If you take <INVENTED NAME> on a long-term basis (longer than 1 year) your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

During treatment

If severe or persistent diarrhoea occurs during treatment with <INVENTED NAME> contact your doctor immediately, as lansoprazole has been associated with a small increase in infectious diarrhoea.

Other medicines and <INVENTED NAME>

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

In particular tell your doctor if you are taking medicines containing any of the following:
- HIV protease inhibitors such as atazanavir and nelfinavir (used to treat HIV),
- methotrexate (used to treat autoimmune disease and cancer),
- ketoconazole (used to treat Cushing's syndrome – when the body produces an excess of cortisol),
- itraconazole (used to treat fungal infections),
- rifampicin (used to treat tuberculosis),
- digoxin (used to treat heart problems),
- warfarin (used to treat blood clots),
- theophylline (used to treat asthma),
- tacrolimus (used to prevent transplant rejection),
- fluvoxamine (used to treat depression and other psychiatric conditions),
- antacids (used to treat heartburn or acid regurgitation such as aluminium hydroxide or magnesium carbonate),
- sucralfate (used for healing ulcers),
- St John´s wort (*Hypericum perforatum*) (used to treat mild depression).

Pregnancy and breast-feeding

The use of <INVENTED NAME> during pregnancy is not recommended as there is no data available.

It is not known if lansoprazole is present in breast milk. Discuss with your doctor whether it is more beneficial for you to continue taking this medicine or for you to breast-feed your child.

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

Side effects such as dizziness, vertigo (a spinning sensation when sitting or standing still), feeling sleepy and problems with your sight sometimes occur in patients taking lansoprazole. If you experience side effects like these you should take caution as your ability to react may be decreased.

You alone are responsible to decide if you are in a fit condition to drive a motor vehicle or perform other tasks that demand increased concentration. Because of their effects or undesirable effects, one of the factors that can reduce your ability to do these things safely is your use of medicines.

Descriptions of these effects can be found in other sections. Read all the information in this leaflet for guidance. Discuss with your doctor or pharmacist if you are unsure about anything.

<INVENTED NAME> contains sucrose, aspartame and sodium
This medicine contains 5.97 mg of aspartame per tablet.
This medicine contains 11.93 mg of aspartame per tablet.

Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

This medicine contains sucrose.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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

3. How to take <INVENTED NAME>

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The dose of <INVENTED NAME> depends on your condition. The recommended doses of <INVENTED NAME> for adults are given below. Your doctor will sometimes prescribe you a different dose and will tell you how long your treatment will last.

Treatment of heartburn and acid regurgitation: one 15 mg or 30 mg orodispersible tablet every day for 4 weeks. If symptoms persist you should report to your doctor. If your symptoms are not relieved within 4 weeks, please contact your doctor.

Treatment of duodenal (gut) ulcer: one 30 mg orodispersible tablet every day for 2 weeks.

Treatment of stomach ulcer: one 30 mg orodispersible tablet every day for 4 weeks.

Treatment of inflammation in your food pipe (reflux oesophagitis): one 30 mg orodispersible tablet every day for 4 weeks.

Long-term prevention of reflux oesophagitis: one 15 mg orodispersible tablet every day, your doctor may adjust your dose to one 30 mg orodispersible tablet every day.

Treatment of infection caused by *Helicobacter pylori*: The recommended dose is one 30 mg orodispersible tablet in combination with two different antibiotics in the morning and one 30 mg orodispersible tablet in combination with two different antibiotics in the evening. Treatment will usually be every day for 7 days.

The recommended combinations of antibiotics are:
- 30 mg <INVENTED NAME> together with 250-500 mg clarithromycin and 1,000 mg amoxicillin,
- 30 mg <INVENTED NAME> together with 250 mg clarithromycin and 400-500 mg metronidazole.

If you are being treated for infection because you have an ulcer, it is unlikely that your ulcer will return if the infection is successfully treated. To give your medicine the best chance of working, take it at the right time and do not miss a dose.

Treatment of duodenal (gut) or stomach ulcer in patients requiring continued non-steroidal anti-inflammatory drug (NSAID) treatment: one 30 mg orodispersible tablet every day for 4 weeks.

Prevention of duodenal (gut) or stomach ulcer in patients requiring continued NSAID treatment: one 15 mg orodispersible tablet every day, your doctor may adjust your dose to one 30 mg orodispersible tablet every day.

Zollinger-Ellison syndrome: The recommended dose is two 30 mg orodispersible tablets every day to start with, then depending on how you respond to **<INVENTED NAME>** the dose that your doctor decides is best for you.

Use in patients with liver problems
If you have moderate or severe problems with your liver your doctor may give you half the recommended dose.

Use in elderly
Your doctor may give you less than the recommended dose if you are elderly. The recommended maximum dose for elderly patients is 30 mg a day.

Use in children:
<INVENTED NAME> should not be given to children.

How to take

For the best results from your medicines you should take <INVENTED NAME> at least 30 minutes before food.

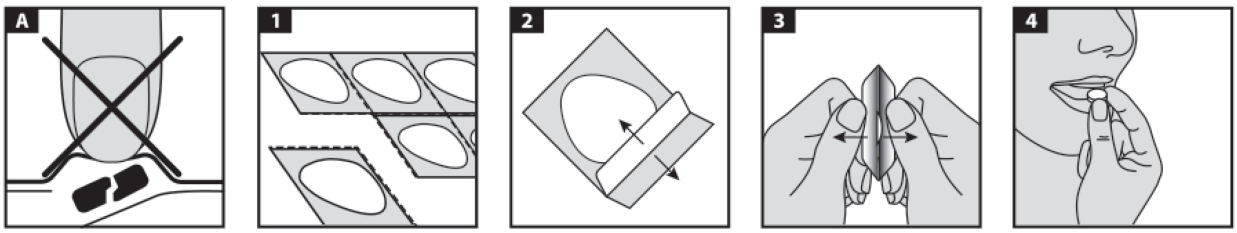
If you are taking **<INVENTED NAME>** once a day, try to take it at the same time each day. You may get best results if you take **<INVENTED NAME>**n first thing in the morning.

If you are taking <INVENTED NAME> twice a day, you should have the first dose in the morning and the second dose in the evening.

<INVENTED NAME> breaks easily, so you should handle the tablets carefully. Do not handle the tablets with wet hands as the tablets may break up.

<INVENTED NAME> may be available in push-through or peelable blisters.
1. For **peelable blisters only**, hold the blister strip at the edges and separate one blister cell from the rest of the strip by gently tearing along the perforations around it.
2. Carefully peel off the backing. For non-perforated blisters, take care not to peel off the backing of adjacent tablets.
3. Gently push the tablet out.
4. Put the tablet in your mouth. It will dissolve directly in your mouth, so that it can be easily swallowed.

You can also swallow the tablet whole with a glass of water.



Your doctor might instruct you to take the tablet with a syringe, in case you have serious difficulties with swallowing.

If you use an oral syringe:

- Remove the plunger of the syringe (at least 5 ml syringe for the 15 mg tablet and 10 ml syringe for the 30 mg tablet).
- Put the tablet into the barrel.
- Put the plunger back onto the syringe.
- For the 15 mg tablet: Draw 4 ml tap water into the syringe.

- For the 30 mg tablet: Draw 10 ml tap water into the syringe.
- Turn the syringe upside down and draw an additional 1 ml of air into it.
- Shake the syringe gently for 10-20 seconds until the tablet is dispersed.
- The contents can be emptied directly into the mouth.
- Refill the syringe with 2-5 ml of tap water to flush the remnants out of the syringe into the mouth.
- Repeat the last step if necessary.

If you use a nasogastric tube:

It is important that the appropriateness of the selected tube is carefully tested. The recommended diameter of nasogastric tube to be used is 3.3 mm (size 10 French) or larger.

- Remove the plunger of the syringe (use at least a 25 ml syringe for the 15 mg tablet and a 50 ml syringe for the 30 mg tablet).
- Put the tablet into the barrel.
- Put the plunger back onto the syringe.
- For the 15 mg tablet: Draw 10 ml tap water into the syringe.
- For the 30 mg tablet: Draw 25 ml tap water into the syringe.
- Turn the syringe upside down and draw an additional 5 ml of air into it.
- Shake the syringe gently for 10-20 seconds until the tablet is dispersed.
- Join the syringe to the tube and empty the syringe contents into the nasogastric tube.
- For the 15 mg tablet: Refill the syringe with 10 ml of tap water and empty the syringe contents into the tube.
- For the 30 mg tablet: Refill the syringe with 25 ml of tap water and empty the syringe contents into the tube.

If you take more <INVENTED NAME> than you should
If you take more **<INVENTED NAME>** than you have been told to, seek medical advice quickly.

If you forget to take <INVENTED NAME>
If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose. If this happens do not take the missed dose and continue taking <INVENTED NAME> as normal.
Do not take a double dose to make up for a forgotten tablet.

If you stop taking <INVENTED NAME>
Do not stop treatment early because your symptoms have got better. Your condition may not have been fully healed and may reoccur if you do not finish your course of treatment.

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

4. Possible side effects

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

If you think you may have any of the following serious side effects, stop taking this medicine and contact your doctor or go to your nearest hospital emergency room immediately.

- Very rarely <INVENTED NAME> may cause severe hypersensitivity (allergic) reactions. Symptoms of a hypersensitivity reaction may include fever, rash, swollen face, swollen lymph nodes, swollen tongue or pharynx, difficulty to swallow, hives, difficulty to breath and sometimes a fall in blood pressure.
- Very rarely, severe skin reactions that may be life threatening have been reported with <INVENTED NAME>. Symptoms include reddish patches on the trunk, the patches are target-like macules or circular, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms [Stevens-Johnsons Syndrome (SJS), Toxic Epidermal Necrolysis (TEN)].

- Widespread rash, high body temperature and enlarged lymph nodes [Drug Reaction with
- Eosinophilia and Systemic Systems (DRESS, frequency not known)].
- If you take <INVENTED NAME> 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.
- Very rarely <INVENTED NAME> may cause a reduction in the number of white blood cells (agranulocytosis) and your resistance to infection may be decreased or coexisting abnormal reductions in the number of red and white blood cells, as well as platelets (pancytopenia). If you experience an infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems, or experience tiredness, pale skin with unexplained bruising or bleeding for longer than normal, you should see your doctor immediately. A blood test will be taken to check possible reduction of blood cells.
- Rarely <INVENTED NAME> may cause inflammation of the pancreas (pancreatitis) and its symptoms include sudden intense pains in the middle of the upper abdomen that may radiate to the back, which may lead to nausea and vomiting.
- If severe or persistent diarrhoea occurs during the treatment with <INVENTED NAME> contact your doctor immediately, as <INVENTED NAME> has been associated with a small increase in infectious diarrhoea.

Other possible side effects:

Common (may affect up to 1 in 10 people):
- headache, dizziness,
- diarrhoea, constipation, stomach pains, feeling sick (nausea) or being sick (vomiting), wind, dry or sore mouth or throat,
- skin rash, itching,
- changes in liver function test values,
- tiredness,
- benign polyps in the stomach.

Uncommon (may affect up to 1 in 100 people):
- depression,
- joint or muscle pain,
- fluid retention or swelling,
- changes in blood cell counts,
- risk of hip, wrist and spine fracture.

Rare (may affect up to 1 in 1,000 people):
- fever,
- restlessness, drowsiness,
- confusion, hearing, seeing or feeling things that aren’t there (hallucinations), problems sleeping (insomnia),
- visual disturbances,
- a spinning sensation when standing still (vertigo),
- a change in the way things taste, loss of appetite, inflammation of your tongue (glossitis),
- skin reactions such as burning or pricking feeling under the skin, bruising, reddening and excessive sweating,
- sensitivity to light,
- hair loss,
- feelings of ants creeping over the skin (paraesthesia), trembling,
- anaemia (paleness),

- inflammation of the kidneys (tubulointerstitial nephritis), possible symptoms include changes in amount of urine, blood in urine,
- inflammation of the liver (may be seen as yellow skin or eyes),
- breast swelling in males, impotence.
- candidiasis (fungal infection, may affect esophagus mucosa).

Very rare (may affect up to 1 in 10,000 people):
- inflammation of your mouth (stomatitis),
- bowel inflammation (colitis),
- increase in test values such as cholesterol and triglyceride levels,
- low levels of sodium in the blood, symptoms include nausea and vomiting, headache, drowsiness and fatigue, confusion, muscle weakness or spasms, irritability, seizures, coma. Your doctor may decide to perform regular blood tests to monitor your levels of sodium.

Frequency not known (frequency cannot be estimated from the available data):
- skin related forms of lupus or lupus rash,
- rash, possibly with pain in the joints,
- visual hallucinations.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [to be completed nationally]. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <INVENTED NAME>

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

Store in the original container in order to protect from moisture.

Bottles: Use within 100 days of opening. Keep the bottle tightly closed in order to protect from moisture.

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

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 <INVENTED NAME> contains

The active substance is lansoprazole
The other ingredients are sugar spheres, light magnesium carbonate (E504); crospovidone (E1202); hydroxypropylcellulose (E463); methacrylic acid - ethyl acrylate, copolymer (1:1); triethyl citrate (E1505); sodium hydroxide (E524); talc (E553b); polysorbate (E433); macrogol; iron oxide red (E172); iron oxide yellow (E172); mannitol (E421); microcrystalline cellulose (E460); sodium starch glycolate; aspartame (E951); sodium laurilsulfate; sodium hydrogen carbonate (E500); citric acid monohydrate (E330); strawberry flavour and magnesium stearate. (see section 2 ‘<INVENTED NAME> contains sucrose, aspartame and sodium’

What <INVENTED NAME> looks like and contents of the pack

Your medicine is in the form of orodispersible tablets (solid oral dosage form) which disperse to release gastro-resistant microgranules.

<INVENTED NAME> 15 mg orodispersible tablets are white to yellowish white with orange to dark brown speckles, round, flat-faced beveled edged tablet engraved with “LP1” on one side and “M” on other side.

<INVENTED NAME> 30 mg orodispersible tablets are white to yellowish white with orange to dark brown speckles, round, flat-faced beveled edged tablet engraved with “LP2” on one side and “M” on other side.

<INVENTED NAME> 15mg and 30 mg orodispersible tablets are available in:
- blister packs (peelable) of 7, 14, 28, 30, 56, 90 or 98 tablets;
- unit-dose blister packs (peelable) containing 28 x 1 tablets;
- blister packs (push-through) of 7, 14, 28, 30, 56, 90 or 98 tablets;
- unit-dose blister packs (push-through) containing 28 x 1 tablets;
- unit-dose blister packs (push-through) containing 14 x 1 tablets;
- plastic bottles with absorbent cotton and screw caps containing 30, 100 or 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA and United Kingdom (Northern Ireland) under the following names:

Name of Medicinal Product	**Member state**
Lansoprazole 15mg & 30mg orodispersible tablet	Malta
Lansoprazol FLAS VIATRIS 15 mg & 30 mg comprimidos bucodispersables EFG	Spain
Lansoprazole Viatris 15 mg & 30 mg comprimé orodispersible	France
Lansoprazolo Mylan Generics Italia	Italy
Lansoprazole 15mg & 30mg Orodispersible tablets	United Kingdom
Lansoprazol Viatris, 15 mg & 30 mg munsönderfallande tablett	Sweden
Lansoprazol Mylan	Portugal

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