

Package leaflet: Information for the patient

Razolager 15 mg hard gastro-resistant capsules Razolager 30 mg hard gastro-resistant capsules 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 Razolager is and what it is used for
2. What you need to know before you take Razolager
3. How to take Razolager
4. Possible side effects
5. How to store Razolager
6. Contents of the pack and other information

1. What Razolager is and what it is used for

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

Razolager is used to treat adults.

Your doctor may prescribe Razolager for the following conditions:

- Treatment of ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer)
- Treatment of inflammation in your oesophagus (reflux oesophagitis)
- Prevention of reflux oesophagitis
- Treatment of Gastro-oesophageal reflux disease causing heartburn and acid regurgitation
- Treatment of infections caused by the bacteria *Helicobacter pylori* when given in combination with antibiotic therapy
- Treatment or prevention of ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer) in patients requiring continued NSAID treatment (NSAID treatment is used against pain or inflammation)
- Treatment of Zollinger-Ellison syndrome (a growth in the pancreas causing too much acid in the stomach).

2. What you need to know before you take Razolager

Do not take Razolager

- 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 Razolager if:

- you have moderate or severe liver disease. The doctor may have to adjust your dosage.

- you have ever had a skin reaction after treatment with a medicine similar to lansoprazole that reduces stomach acid.
- you are due to have a specific blood test (Chromogranin A).
- you have low vitamin B12 levels or have risk factors for low vitamin B12 levels and receive long-term treatment with lansoprazole. As with all acid reducing agents, lansoprazole may lead to a reduced absorption of vitamin B12.
- Serious skin reactions [Stevens-Johnson syndrome, toxic epidermal necrolysis, and drug reaction with eosinophilia and systemic symptoms (DRESS)] have been reported in association with Razolager treatment. Stop using Razolager and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.
- When taking lansoprazole, 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 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.

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

If your doctor has given you lansoprazole in addition to other medicines intended for the treatment of *Helicobacter pylori* infection (antibiotics) or together with anti-inflammatory medicines to treat your pain or rheumatic disease, please read the package leaflets of these medicines carefully.

When taking lansoprazole, 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.

Taking a proton pump inhibitor like lansoprazole, 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).

During treatment

If diarrhoea occurs during the treatment with lansoprazole contact your doctor immediately, as lansoprazole has been associated with a small increase in infectious diarrhoea.

If you take Razolager 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.

Children and adolescents

Razolager should not be given to children and adolescents.

Other medicines and Razolager

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular tell your doctor if you are taking medicines containing any of the following active substances as lansoprazole may affect the way these drugs work:

- HIV protease inhibitors such as atazanavir and nelfinavir (used to treat HIV)
- methotrexate (used to treat autoimmune diseases and cancer)
- ketoconazole, itraconazole, rifampicin (used to treat infections)
- 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 diseases)
- antacids (used to treat heartburn or acid regurgitation)
- sucralfate (used for healing ulcers)
- St John's wort (*Hypericum perforatum*) (used to treat mild depression)

Pregnancy and breast-feeding

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.

Pregnancy

The use of lansoprazole is not recommended during pregnancy.

Breast-feeding

Your doctor will decide whether you can take lansoprazole if you are breast-feeding. It is not known whether lansoprazole may pass into breast milk.

Driving and using machines

Side effects such as dizziness, vertigo, drowsiness and visual disturbances sometimes occur in patients taking lansoprazole. If you experience side effects like those you should take caution as your ability to react may be decreased. If you are affected, do not drive or operate machines.

Razolager contains sucrose and sodium.

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 capsule, that is to say essentially 'sodium-free'.

3. How to take Razolager

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

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

Treatment of Gastro-oesophageal reflux disease causing heartburn and acid regurgitation:

The recommended dose is 15 mg or 30 mg 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 ulcers in the upper part of the intestine (duodenal ulcer):

The recommended dose is 30 mg every day for 2 weeks. If you are not fully healed within this time, your doctor may tell you to take the same dose for another 2 weeks.

Treatment of stomach ulcer (gastric ulcer):

The recommended dose is 30 mg every day for 4 weeks. If you are not fully healed within this time, your doctor may tell you to take the same dose for another 4 weeks.

Treatment of inflammation in your oesophagus (reflux oesophagitis):

The recommended dose is 30 mg every day for 4 weeks. If you are not fully healed within this time, your doctor may tell you to take the same dose for another 4 weeks.

Long-term prevention of reflux oesophagitis:

The recommended dose is 15 mg every day, your doctor may adjust your dose to 30 mg every day if needed.

Treatment of infection of *Helicobacter pylori*:

The recommended dose is 30 mg in combination with two different antibiotics in the morning and 30 mg in combination with two different antibiotics in the evening. Treatment will usually be every day for 7 days.

The recommended combination of antibiotics are:

- 30 mg lansoprazole together with 250 to 500 mg clarithromycin and 1000 mg amoxicillin twice a day
- 30 mg lansoprazole together with 250 mg clarithromycin and 400 to 500 mg metronidazole twice a day.

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 ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer) in patients requiring continued NSAID treatment:

The recommended dose is 30 mg every day for 4 weeks. If you are not fully healed within this time, your doctor may tell you to take the same dose for another 4 weeks. In case your ulcer still doesn't heal your doctor may decide for a longer course of treatment and/or higher dose.

Prevention of ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer) in patients requiring continued NSAID treatment:

The recommended dose is 15 mg every day, your doctor may adjust your dose to 30 mg every day.

Treatment of Zollinger-Ellison syndrome:

The recommended dose is 60 mg every day to start with, then depending on how you respond to lansoprazole the dose that your doctor decides is best for you. If your doctor recommends that you take more than 120 mg daily, you should take half the daily dose in the morning and half the daily dose in the evening.

Patient with impaired liver function

If you have moderate to severe liver disease your doctor may recommend a lower dose of lansoprazole and perform regular check-up.

Taking this medicine

Swallow the capsule whole with a glass of water. If you find the capsules difficult to swallow your doctor may advise on alternative ways to take your medicine. Do not crush or chew these capsules or the content of an emptied capsule because this will stop them from working properly.

If you are taking Razolager once a day, try to take it at the same time each day. You may get best results if you take Razolager first thing in the morning. You should take your medicine at least 30 minutes before you eat.

If you are taking Razolager twice a day, you should have the first dose in the morning and the second dose in the evening.

If you take more Razolager than you should

If you take more Razolager than you have been told to, talk to your doctor or pharmacist straight away.

If you forget to take Razolager

If you forget to take a dose, take the next dose as soon as you remember unless it is nearly time for your next dose. **Do not** take a double dose to make up for a forgotten dose.

If you stop taking Razolager

Do not stop treatment early because your symptoms have got better. Your condition may not have

fully healed and may recur 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.

Stop taking your medicine and tell your doctor immediately or go to your nearest hospital emergency if you suffer from any of the following:

Uncommon: may affect up to 1 in 100 people

- 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 you should see your doctor immediately. A blood test will be taken to check possible reduction of white blood cells (agranulocytosis or leucopenia).

Rare: may affect up to 1 in 1,000 people

- inflammation of your pancreas which may include signs such as severe pain in your tummy, loss of appetite, feeling or being sick, swollen abdomen (pancreatitis).
- inflammation of the liver, which may be seen as yellow skin or eyes, pale stools and dark urine.

Very rare: may affect up to 1 in 10,000 people

- very severe skin reactions with reddening of the skin with blisters or peeling, blistering and bleeding in the lips, eyes, mouth, nose and genitals, severe inflammation and skin loss. This could be Stevens-Johnson syndrome or toxic epidermal necrolysis.
- a reduction in the number of white or red blood cells or platelets which may lead to tiredness, paleness, more frequent infections (such as throat and mouth ulcers) or you may have bleeding or bruising more easily than normal (pancytopenia).
- severe hypersensitivity reactions including shock. Symptoms of hypersensitivity may include sudden signs of allergy such as fever, skin rash, itchy or hives on the skin, swollen face, tongue or throat, difficulty in breathing or swallowing and sometimes a fall in blood pressure.

Not known: frequency cannot be estimated from the available data

- extensive rash, high body temperature and enlarged lymph nodes (drug reaction with eosinophilia and systemic symptoms (DRESS)).

Other side effects

Tell your doctor if you suffer from long-lasting or severe diarrhoea. Your doctor may want to change your medicine.

Common: may affect up to 1 in 10 people

- headache, dizziness,
- diarrhoea, constipation, stomach pains, feeling or being sick, wind, dry mouth or throat,
- skin rash, itching, hives,
- 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,
- fracture of the hip, wrist or spine,
- fluid retention or swelling,
- reduction in blood platelets resulting in bleeding or bruising more easily than normal (thrombocytopenia),
- increase in certain type of white blood cells which may be seen in blood tests (eosinophilia).

Rare: may affect up to 1 in 1,000 people

- fever,
- restlessness, drowsiness, confusion, hallucinations, insomnia, visual disturbances, 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 (paraesthesiae), trembling,
- anaemia (paleness and tiredness),
- passing less urine than usual or being unable to pass urine, blood or mucous in the urine, pain in the lower back possibly with rash, fever, feeling tired, being sick. These may be signs of kidney diseases,
- fungal infection of your food pipe,
- breast swelling in males, impotence.

Very rare: may affect up to 1 in 10,000 people

- inflammation of your mouth (stomatitis),
- colitis (bowel inflammation),
- decrease in blood sodium levels which may be seen in blood tests,
- increase in level of blood fats which may be seen in blood tests.

Not known: frequency cannot be estimated from the available data

- rash, possibly with pain in the joints
 - visual hallucinations
- If you are on lansoprazole 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.

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 HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Razolager

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/carton after “EXP”. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from moisture.

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 Razolager contains

- The active substance is lansoprazole. Each gastro-resistant capsule contains either 15 mg or 30 mg of lansoprazole.
- The other ingredients are gastro-resistant granules containing sugar spheres (maize starch and sucrose), sodium laurilsulphate, meglumine, mannitol, hypromellose, macrogol, talc, polysorbate 80, titanium dioxide (E171) and methacrylic acid-ethyl acrylate co-polymer 1:1. The capsule shell contains gelatin, titanium dioxide (E171), and sodium laurilsulfate. The 15 mg capsules also contain quinoline yellow (E104).

What Razolager looks like and contents of the pack

The 15 mg capsules are opaque yellow containing white to off white spherical micro-granules
The 30 mg capsules are opaque white containing white to off white micro-granules.

The capsules are available in blister packs of 7, 14, 15, 28, 30, 35, 56, 60 and 98 capsules. Also available in calendar packs 28 or 98 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Viatrix Limited, Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland

Manufacturer:

Laboratories Liconsa, S.A.

Avenida Miralcampo 7, Poligono Industrials De Miralcampo, 19200 Azuqueca de Henares (Guadalajara)
Spain

Mylan Hungary Kft/Mylan Hungary Ltd

Mylan utca 1, Komárom,

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

Denmark: Lansoprazol Viatrix 15 mg, harde enterokapslar

Lansoprazol Viatrix 30 mg, harde enterokapslar

Ireland: Razolager 15 mg hard gastro-resistant capsules

Razolager 30 mg hard gastro-resistant capsules

Italy: Lansoprazolo Mylan Generics

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