

Package leaflet: Information for the patient

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

1. What Lansoprazole Mylan 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.

Your doctor may prescribe Lansoprazole Mylan for the following conditions:

- Treatment of duodenal and stomach ulcers
- Treatment of inflammation in your oesophagus (reflux oesophagitis)
- Prevention of reflux oesophagitis
- Treatment of heartburn and acid regurgitation
- Treatment of infections caused by the bacteria *Helicobacter pylori* when given in combination with antibiotic therapy
- Treatment or prevention of duodenal or stomach ulcer in patients requiring continued NSAID treatment (NSAID treatment is used against pain or inflammation)
- Treatment of Zollinger-Ellison syndrome.

Your doctor may have prescribed Lansoprazole Mylan for another indication or with a dose different from that which is written in this information leaflet. Please follow your doctor's instructions for taking your medicine.

2. What you need to know before you take Lansoprazole

Do not take Lansoprazole Mylan

- if you are allergic to lansoprazole or any of the other ingredients of this medicine (listed in section 6).
- if you are taking anti-viral medicine called atazanavir (used in the treatment of HIV).

Warnings and precautions

Talk to your doctor or pharmacist before taking Lansoprazole:

- 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 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.

Please tell your doctor if you have serious liver disease. The doctor may have to adjust your dosage.

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

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 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.

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).

If you take Lansoprazole Mylan 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.

Other medicines and Lansoprazole

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 active substances:

- atazanavir (used to treat HIV infection). Do not take lansoprazole with atazanavir (see 'Do not take Lansoprazole')
- ketoconazole, itraconazole, rifampicin (used to treat infections)
- digoxin (used to treat heart problems)
- 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)

Lansoprazole Mylan with food and drink

For the best results from your medicine take Lansoprazole Mylan at least 30 minutes before food.

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.

Driving and using machines

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

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 (see section 4).

Lansoprazole Mylan 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.

3. How to take Lansoprazole

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 Lansoprazole Mylan depends on your condition. The recommended doses of Lansoprazole Mylan 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 heartburn and acid regurgitation: one 15 mg or 30 mg capsule 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 ulcer: one 30 mg capsule every day for 2 weeks

Treatment of stomach ulcer: one 30 mg capsule every day for 4 weeks

Treatment of inflammation in your oesophagus (reflux oesophagitis): one 30 mg capsule every day for 4 weeks

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

Treatment of infection of *Helicobacter pylori*: The recommended dose is one 30 mg capsule in combination with two different antibiotics in the morning and one 30 mg capsule 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 Mylan together with 250-500 mg clarithromycin and 1000 mg amoxicillin
- 30 mg Lansoprazole Mylan 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 or stomach ulcer in patients requiring continued NSAID treatment: one 30 mg capsule every day for 4 weeks.

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

Zollinger-Ellison syndrome: The usual dose is two 30 mg capsules every day to start with, then depending on how you respond to Lansoprazole the dose that your doctor decides is best for you.

Method of administration

Swallow the capsule whole with a glass of water before food. 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 Lansoprazole once a day, try to take it at the same time each day. You may get best results if you take Lansoprazole first thing in the morning.

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

Use in children

Lansoprazole should not be given to children.

If you take more Lansoprazole Mylan than you should

If you take more Lansoprazole Mylan than you have been told to, seek medical advice quickly.

If you forget to take Lansoprazole Mylan

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 Lansoprazole Mylan

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:

- Diarrhoea (common, may affect up to 1 in 10 people). This side effect should be reported to your doctor as this medicine has been associated with a small increase in infectious diarrhoea.
- A reduction in the number of white blood cells and your resistance to infection may be decreased. 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 (uncommon, may affect up to 1 in 100 people).

- Inflammation of the pancreas which causes severe pain in the abdomen and back (pancreatitis) (rare, may affect up to 1 in 1,000 people).
- Inflammation of the liver, which may be seen as yellow skin or eyes (jaundice) (rare, may affect up to 1 in 1,000 people).
- Angioedema, with symptoms such as: swollen face, tongue or pharynx, difficulty to swallow, hives and difficulty breathing (rare, may affect up to 1 in 1,000 people).
- Kidney problems (rare, may affect up to 1 in 1,000 people).
- A reduction in all types of blood cells which you may see as an increase of infections (see leucopenia above), unusual bruising or bleeding for longer than normal together with paleness and tiredness (very rare, may affect up to 1 in 10,000 people).
- Severe hypersensitivity reactions including shock. Symptoms of a hypersensitivity reaction may include fever, rash, swelling and sometimes a fall in blood pressure (very rare, may affect up to 1 in 10,000 people).
- Very severe skin reactions with reddening, blistering, severe inflammation and skin loss (Stevens-Johnson syndrome) (very rare, may affect up to 1 in 10,000 people).
- Colitis (bowel inflammation) (very rare, may affect up to 1 in 10,000 people).
- Rash, possibly with pain in the joints (not known, frequency cannot be estimated from the available data).

Other possible side effects:

Common (may affect up to 1 in 10 people):

- headache, dizziness,
- constipation, stomach pains, feeling or being sick, wind, dry or sore 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,
- an increase in the number of white blood cells which can be seen in a blood test,
- a reduction in the number of blood platelets. You may notice unusual bruising or bleeding of your skin.

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),
- breast swelling in males, impotence,
- candidiasis (fungal infection, may affect skin or the mucosa).

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

- inflammation of your mouth (stomatitis),
- changes in test values such as sodium, cholesterol and triglyceride levels.

Frequency not known (frequency cannot be estimated from the available data):

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, 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 lansoprazole

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

Do not use Lansoprazole Mylan after the expiry date which is stated on the blister, carton, bottle after “EXP”. The expiry date refers to the last day of that month.

Blisters: Do not store above 25°C. Store in the original container in order to protect from light.

Bottles: Do not store above 25°C. Store in the original container in order to protect from light. Use within 30 days of opening. Once open keep bottle tightly closed.

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 Lansoprazole Mylan contains

- Each Lansoprazole 15 mg Gastro-resistant Capsule contains 15 mg of lansoprazole.
Each Lansoprazole 30 mg Gastro-resistant Capsule contains 30 mg of lansoprazole.
- The other ingredients are sugar spheres, magnesium carbonate, sucrose (see section 2 “Lansoprazole Mylan contains sucrose”), maize starch and hydroxypropyl cellulose. The coating and capsule shell contains hydroxypropyl cellulose, methacrylic acid – ethyl acrylate co-polymer, talc, macrogol, titanium dioxide (E171), polysorbate 80, gelatin and silica colloidal anhydrous. The 30 mg capsule shell also contains brilliant blue FCF (E133) and erythrosine (E127). The printing ink contains shellac, ammonia solution concentrated, iron oxide black (E172) and potassium hydroxide.

What Lansoprazole Mylan looks like and contents of the pack

15 mg: white to off-white coloured pellets filled in a hard gelatin capsule of size 2 with white opaque cap and white opaque body printed with ‘MYLAN’ over ‘LN 15’ on both cap and body in black ink.

30 mg: white to off-white coloured pellets filled in a hard gelatin capsule of size 0 with pink opaque cap and pink opaque body printed with ‘MYLAN’ over ‘LN 30’ on both cap and body in black ink.

Lansoprazole Mylan is available in blister packs of 7, 14, 15 (15 mg only), 28, 28 x 1, 30, 56, 60, 84, 98, 100 and 500 capsules and in multipacks of 84 and 98 comprising of 2 cartons each containing 42 and 49 capsules, and bottles of 7, 14, 28, 30, 56, 60, 84, 98, 100 and 500 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Ltd
t/a Gerard Laboratories,
35/36 Baldoyle Industrial Estate,
Grange Road, Dublin 13

Manufacturer(s)

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35/36 Baldoyle Industrial Estate,
Grange Road, Dublin 13

Mylan Hungary Kft, H-2900,
Komárom, Mylan útca.1, Hungary

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

Name of Medicinal Product	Member state
Lansoprazole 15 mg & 30 mg gastro-resistant capsules	United Kingdom
Lansoprazole Mylan 15 mg & 30 mg gastro-resistant capsules	Ireland
Lansoprazol Mylan 15 mg magensaftresistente Kapseln Lansoprazol Mylan 30 mg magensaftresistente Kapseln	Austria
Lansomylan 15 mg & 30 mg maagsapresistente capsules	Belgium
Lansoprazol Mylan	Portugal
Lansoprazol Mylan 30mg, enterosolventní tvrdé tobolky	Czech Republic
Lansoprazol Mylan 15 mg, maagsapresistente capsules Lansoprazol Mylan 30 mg, maagsapresistente capsules	The Netherlands
Lansolajen 15 mg & 30 mg	Denmark, Iceland, Sweden
Lansoprazol Mylan	Finland, Norway
Lansoprazole Mylan Pharma 15 mg & 30 mg gélule gastro résistante	France
Lansoprazolo Mylan	Italy
Lansoprazol MYLAN Pharmaceuticals 15 mg & 30 mg cápsulas gastroresistentes EFG	Spain

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