

PACKAGE LEAFLET

For medicinal products available on prescription

PACKAGE LEAFLET: INFORMATION FOR THE USER
Lansoprazole Pinewood 15 mg Gastro-Resistant Hard Capsules
Lansoprazole Pinewood 30 mg Gastro-Resistant Hard 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 Pinewood is and what it is used for
2. What you need to know before you take Lansoprazole Pinewood
3. How to take Lansoprazole Pinewood
4. Possible side effects
5. How to store Lansoprazole Pinewood
6. Contents of the pack and other information

1. What Lansoprazole Pinewood is and what it is used for

The active ingredient in Lansoprazole Pinewood 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 Pinewood for the following indications:

- Treatment of duodenal and stomach ulcer
- 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 Pinewood 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 Pinewood

Do not take Lansoprazole Pinewood

- if you are allergic (hypersensitive) to lansoprazole or any of the other ingredients of this medicine (listed in section 6).
- if you are taking a medicine containing the active substance atazanavir (used in the treatment of HIV).

Warnings and precautions

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 Pinewood contact your doctor immediately, as Lansoprazole Pinewood has been associated with a small increase in infectious diarrhoea.

If your doctor has given you Lansoprazole Pinewood 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 also read the package leaflets of these medicines carefully.

If you take Lansoprazole Pinewood 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.

Talk to your doctor before taking Lansoprazole Pinewood:

- if you have ever had a skin reaction after treatment with a medicine similar to Lansoprazole Pinewood 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 Pinewood. Remember to also mention any other ill-effects like pain in your joints.

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.

Other medicines and Lansoprazole Pinewood

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 Pinewood may affect the way these drugs work:

- 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 Pinewood with food, drink and alcohol

For the best results from your medicines you should take Lansoprazole Pinewood at least 30 minutes before food.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Use of Lansoprazole Pinewood is not recommended during pregnancy, as there is no adequate experience on the use of lansoprazole during pregnancy.

There is insufficient experience with use of lansoprazole during breast-feeding. Based on the results of animal studies, it is thought that Lansoprazole crosses into the breast milk.

When making a decision as to whether breast-feeding or therapy with Lansoprazole Pinewood should be continued or discontinued, your treating physician will consider the benefits of breast-feeding for your child and the benefits of therapy with Lansoprazole Pinewood for you.

Driving and using machines

Side effects such as dizziness, vertigo, tiredness and visual disturbances sometimes occur in patients taking Lansoprazole Pinewood. 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, nurse or pharmacist if you are unsure about anything.

Important information about some of the ingredients of Lansoprazole Pinewood

Lansoprazole Pinewood 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 Pinewood

The peelable blisters are opened as described following foil opening instructions:

- Remove one blister by tearing down perforations
 - Carefully peel back corner of foil to reveal capsule
- (CAPSULE CANNOT BE PUSHED THROUGH FOIL)



The non-peelable blisters are opened by pushing through the aluminium foil

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

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

The dose of Lansoprazole Pinewood depends on your condition. The usual doses of Lansoprazole Pinewood 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 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 usual 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 combinations of antibiotics are:

- 30 mg Lansoprazole Pinewood together with 250-500 mg clarithromycin and 1000 mg amoxicillin
- 30 mg Lansoprazole Pinewood 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 Pinewood the dose that your doctor decides is best for you.

Lansoprazole Pinewood should not be given to children.

Take your medicine exactly as your doctor has told you. You should check with your doctor if you are not sure how to take your medicine.

If you take more Lansoprazole Pinewood than you should

If you take more Lansoprazole Pinewood than you have been told to, seek medical advice quickly or quickly consult the Toxicological Information Service.

If you forget to take Lansoprazole Pinewood

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 skip the missed dose and take the remaining capsules as normal. Do not take a double dose to make up for a forgotten capsule.

If you stop taking Lansoprazole Pinewood

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, Lansoprazole Pinewood can cause side effects, although not everybody gets them.

The following side effects are common (may affect up to 1 in 10 people)

- headache, dizziness
- diarrhoea, constipation, stomach pains, feeling or being sick, wind, dry or sore mouth or throat
- skin rash, itching
- changes in liver function test values
- tiredness
- benign polyps in the stomach.

The following side effects are uncommon (may affect up to 1 in 100 people):

- depression
- joint or muscle pain
- fluid retention or swelling
- changes in blood cell counts.

The following side effects are rare (may affect up to 1 in 1000 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 (paraesthesia), trembling
- anaemia (paleness)
- kidney problems
- pancreatitis
- inflammation of the liver (may be seen as yellow skin or eyes)
- breast swelling in males, impotence
- candidiasis (fungal infection, may affect skin or the mucosa)
- angioedema; You should see your doctor immediately if you experience symptoms of angioedema, such as swollen face, tongue or pharynx, difficulty to swallow, hives and difficulties to breath.
- taking a proton pump inhibitor like Lansoprazole Pinewood, 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).

The following side effects are very rare (may affect up to 1 in 10000 people) :

- severe hypersensitivity reactions including shock. Symptoms of a hypersensitivity reaction may include fever, rash, swelling and sometimes a fall in blood pressure
- inflammation of your mouth (stomatitis)
- colitis (bowel inflammation)
- changes in test values such as sodium, cholesterol and triglyceride levels
- very severe skin reactions with reddening, blistering, severe inflammation and skin loss.
- very rarely Lansoprazole Pinewood may cause 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 (agranulocytosis).

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

- If you are on Lansoprazole Pinewood 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.

- Rash, possibly with pain in the joints
- Visual hallucinations.

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 HPRAs 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 Lansoprazole Pinewood

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, HDPE bottle and carton. The expiry date refers to the last day of that month.

Peelable and non-peelable OPA- Al-PVC/Alu blister

Do not store above 30°C

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

HDPE bottle with PP screw cap containing silica desiccant

Do not store above 30°C. Use within 6 months of opening

Keep the bottle tightly closed in order to protect from moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Lansoprazole Pinewood contains

- The active substance is lansoprazole

Lansoprazole Pinewood 15 mg gastro-resistant capsules hard are opaque yellow cap and body capsules. Each capsule contains 15 mg of lansoprazole

Lansoprazole Pinewood 30 mg gastro-resistant capsules hard are opaque white cap and body capsules. Each capsule contains 30 mg of lansoprazole

- The other ingredients are:

Capsule content: Sugar spheres (sucrose and maize starch), Sodium laurilsulphate, Meglumine, Mannitol (E421), Hypromellose, Macrogol 6000, Talc, Polysorbate 80, Titanium dioxide (E171), Methacrylic Acid-Ethyl Acrylate Copolymer (1:1), Dispersion 30%

Capsule shell: Gelatin, Titanium dioxide (E171)

Capsule shell of 15 mg also contains: Quinoline yellow (E104)

What Lansoprazole Pinewood looks like and contents of the pack

Lansoprazole 15 mg gastro-resistant capsules are available in blister packs (Peelable or non-peelable OPA- Al-PVC/Alu blister) or HDPE bottle with PP screw cap containing silica desiccant containing 14, 28, 30, 56, 84, 98 and 100 capsules.

Lansoprazole 30 mg gastro-resistant capsules are available in blister packs (Peelable or non-peelable OPA- Al-PVC/Alu blister) or HDPE bottle with PP screw cap containing silica desiccant containing 14, 28, 30, 56, 84, 98 and 100 capsules.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder is:

Pinewood Laboratories Limited

Ballymacarbry

Clonmel

Co. Tipperary

Ireland

The manufacturer is:

LABORATORIOS LICONSA, S.A.

Avda. Miralcampo, Nº 7, Polígono Industrial Miralcampo,

19200 Azuqueca de Henares (Guadalajara),

Spain

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

CZ	Lanxib
DK	Lansopram
IE	Lansoprazole Pinewood 15/30 mg gastro-resistant capsules, hard
NL	Lansoprazol Liconsa 15 mg maagsapersistentente capsules
SE	Lansoprazol Medical Valley

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