FRONT SIDE / PLEASE INCLUDE YOUR DESIGN ON THIS AREA

Package leaflet: Information for the user

Lansoprazole 15 mg gastro-resistant capsules
Lansoprazole 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. WHAT LANSOPRAZOLE GASTRO-RESISTANT CAPSULES IS AND WHAT IT IS USED FOR

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

Your doctor may prescribe this medicine for the following indications:
- Healing ulcers in your stomach or duodenum (gut)
- Healing and preventing ulcers caused by medicines called Non-Steroidal Anti -Inflammatory Drugs (NSAIDs). This includes medicines like aspirin, ibuprofen, ketoprofen and piroxicam
- Gastro-Oesophageal Reflux Disease (GORD). This happens when acid from your stomach escapes into your food pipe (oesophagus) causing damage and irritation

Lansoprazole can relieve symptoms that can happen with the above conditions and stop them from coming back. It can also be used to treat:
- The pain of indigestion or heartburn caused by too much acid (acid-related dyspepsia) in your stomach
- Illnesses, such as Zollinger-Ellison Syndrome, where the stomach makes large amounts of acid. This can lead to diarrhoea and pain in the stomach
- Infections caused by the bacteria Helicobacter pylori when given in combination with antibiotic therapy.

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

You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LANSOPRAZOLE GASTRO-RESISTANT CAPSULES

Do not take Lansoprazole gastro-resistant capsules:
- If you are allergic to lansoprazole or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

Do not take lansoprazole if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Lansoprazole gastro-resistant capsules
- If you have serious liver disease. The doctor may have to adjust your dosage.
- You have osteoporosis or are taking a type of medicine called corticosteroids (which can increase the risk of osteoporosis). 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.
- Your doctor may arrange for you to have an endoscopic examination (where a very small camera is inserted down your oesophagus (food pipe) to look into your stomach). This will help find out what is causing your symptoms. It can help to exclude more serious causes of your symptoms such as stomach cancer.
- If diarrhoea occurs during the treatment with Lansoprazole contact your doctor immediately, as this medicine has been associated with a small increase in infectious diarrhoea.
- If your doctor has given you this medicine 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 this medicine 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.
- If you have ever had a skin reaction after treatment with a medicine similar to Lansoprazole that reduces stomach acid.
- 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 lansoprazole and seek medical attention immediately if you notice any of the symptoms described in section 4.
- 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 (reduced bone density) or if your doctor has told you that you are at risk of getting osteoporosis (for example, if you are taking steroids).

If you take 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.

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 side effects like pain in your joints.

If you think any of these apply to you or you are unsure, talk to your doctor or pharmacist before taking lansoprazole. Do this even if they applied only in the past.
- If you are due to have a specific blood test (Chromogranin A).
- When taking lansoprazole, inflammation in your kidneys 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.

This medicine may affect the way that your body absorbs vitamin B12, 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 B12:
- Extreme tiredness or lack of energy
- Pins and needles
- Sore or red tongue, mouth ulcers
- Muscle weakness.
- Disturbed vision
- Problems with memory, confusion, depression

If you think any of these apply to you or you are unsure, talk to your doctor or pharmacist before taking Lansoprazole. Do this even if they applied only in the past.

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. This includes herbal medicines. This is because lansoprazole can affect the way some other medicines work. Also, some medicines can have an effect on the way lansoprazole works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:
- ketoconazole, itraconazole, mifepristone (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)
- HIV protease inhibitors such as atazanavir and nelfinavir (used to treat HIV)
- Methotrexate (used to treat autoimmune disease and cancer)
- Warfarin (used to treat blood clots)

If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Lansoprazole with food, drink and alcohol
For the best results from your medicines you should take Lansoprazole at least 30 minutes before food.

Pregnancy, breast-feeding and fertility
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.

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

Driving and using machines
Side effects such as dizziness, vertigo, tiredness and visual disturbances 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 for deciding if you are in a fit condition to drive 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 of the leaflet.

Read all the information in this leaflet for guidance.
Discuss with your doctor or pharmacist if you are unsure about anything.

Lansoprazole capsules contain sucrose
Lansoprazole gastro-resistant capsules contain sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Information on sodium content
This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially "sodium free".

3. HOW TO TAKE LANSOPRAZOLE GASTRO-RESISTANT CAPSULES

Always take this medicine exactly as your doctor or pharmacist has told you. The dose will depend on your needs and the illness being treated. Check with your doctor or pharmacist if you are not sure.

Taking your medicine
- Swallow your capsules whole with a glass of water. Do not crush or chew the capsules.
- If you are taking lansoprazole once a day, take it at the same time every morning before breakfast.
- If you are taking lansoprazole twice a day, take the first dose in the morning before breakfast and the second dose in the evening.

The usual doses for adults are:
Stomach ulcers:
- One 30 mg capsule every day for 4 weeks

Ulcers of the duodenum:
- One 30 mg capsule every day for 2 weeks to heal the ulcer
- Your doctor may then decide you need one 15mg capsule every day to stop it coming back

Ulcers of the stomach and duodenum caused by an NSAID:
- One 30 mg capsule every day for 4 weeks to heal the ulcer
- Your doctor may then decide to give you one 15mg or 30mg capsule every day to stop the ulcer or your symptoms coming back
- Your doctor will tell you when to stop taking lansoprazole

Preventing an ulcer and relief of symptoms while taking NSAID:
- One 15mg or 30mg capsule every day
- Your doctor will tell you when to stop taking lansoprazole

Treatment of infection of Helicobacter pylori:
The usual dose is one 30 mg capsule or two 15 mg capsules in combination with two different antibiotics in the morning and one 30 mg capsule or two 15 mg capsules 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 together with 250-500 mg clarithromycin and 1000 mg amoxicillin
- 30 mg lansoprazole together with 250 mg clarithromycin and 400-800 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.

Gastro-oesophageal reflux disease:
GORD:
- One 30mg capsule every day for 4 weeks to heal your food pipe (oesophagus) and/or relieve symptoms
- Your doctor may then decide you need one 15mg or 30mg capsule a day to stop your illness coming back

Indigestion caused by too much acid (acid-related dyspepsia):
- One 15mg or 30mg capsule every day for 2 to 4 weeks
- Talk to your doctor once you have completed this course or if your symptoms are not getting

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If you take more lansoprazole than you should
Tell your doctor or go to your nearest hospital straight away. Remember to take with you any lansoprazole capsules that are left and the pack as such. This is so the doctor knows what you have taken.

If you forget to take lansoprazole
If you forget to take a dose, take it as soon as you remember, unless it is time for your next dose. If it is time for your next dose then skip the missed dose and continue with your next dose as normal. Do not take a double dose to make up for a forgotten dose.

If you stop taking lansoprazole
Keep taking the medicine until your doctor tells you to stop. Do not stop taking lansoprazole just because you feel better. If you do stop taking lansoprazole your illness may get worse again.
If you have any further on the use of this medicine, ask your doctor or pharmacist or nurse.

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.
Stop taking lansoprazole and see a doctor or go to a hospital straightaway if:
- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria) This may mean you are having an allergic reaction to this medicine.

Very rarely, severe skin reactions that may be life threatening have been reported with Lansoprazole. Symptoms include: reddish patches on the trunk, flat 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-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN)).
- Widespread rash, high body temperature and enlarged lymph nodes [Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS, frequency not known)]

Very rarely Lansoprazole 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 Lansoprazole may cause a reduction in the number of white blood cells (agranulocytosis) and your resistant infection may be decreased or exceptional 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.
- You get symptoms such as yellowing of your skin or whites of your eyes, tiredness and fever. This may be due to inflammation of the liver or changes in the way your liver is working

While these are serious side effects that require urgent medical attention, they are all rare or very rare (affect up to 1 in 1000 people).
Talk to your doctor as soon as possible if:
- You get long lasting diarrhoea and keep being sick. This can happen because lansoprazole lowers the natural acid in your stomach which would normally help to kill bacteria. This can lead to stomach infections.
- You get severe stomach pain which may reach through to your back. This could be a sign of pancreatitis.
- You have difficulty in passing water (urine) or you notice blood in your urine. This may be due to kidney problems or changes in the way your kidneys are working.
- You bruise more easily than usual or you get more infections than usual. This could be due to a blood problem. Your doctor may want to carry out a blood test.

If any of the following side effects gets serious or lasts longer than a few days, tell your doctor or pharmacist.
Common (affects up to 1 in 10 people)
- headaches, feeling dizzy or tired, or a general feeling of being unwell
- diarrhoea, constipation, stomach pains, feeling sick (nausea) or being sick (vomiting), wind
- dry or sore mouth or throat, benign polyps in the stomach
- skin rash, itching
- changes in the way your liver is working (shown by a blood test)

Uncommon (affects up to 1 in 100 people)
- low mood (depression)
- joint or muscle pain
- water retention which may cause swollen arms or legs
- fracture of the hip, wrist or spine (if lansoprazole is used in high doses and on a long period of time)
- changes in blood cell counts

Rare (affects up to 1 in 1000 people)
- fever
- feeling restless, drowsy or confused
- seeing or hearing things which are not there (hallucinations)
- numbness, tingling, pricking, burning or creeping on the skin (paresthesia)
- difficulty sleeping (insomnia)
- problems with your vision
- feeling dizzy, possibly with a "spinning" feeling (vertigo)
- taste disturbance, loss of appetite (anorexia), inflammation of your tongue (glossitis)
- skin reactions such as burning or pricking feeling under the skin, bruising, red or purple spots which may be itchy or blister.

excessive sweating
- being more sensitive to the sun than usual
- hair loss (alopecia)
- trembling
- feeling tired, faint, dizzy, having pale skin. These could be symptoms of anaemia.
- 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)
- swelling of the breasts in men (gynaecomastia), being unable to get or keep an erection (impotence)
- candidiasis fungal infection, such as thrush, which may affect your oesophagus (food pipe)

Very rare (affects up to 1 in 10,000 people)
- inflammation of your mouth (stomatitis)
- colitis (bowel inflammation e.g. diarrhoea, abdominal pain, cramping, fever and fatigue, blood in stools)
- 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.

Not known (frequency cannot be estimated from the available data)
- skin-related forms of lupus or a lupus rash, possibly with pain in the joints.
- 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.
- 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 the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in Google Play or Apple App Store.By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE LANSOPRAZOLE GASTRO-RESISTANT CAPSULES

- Keep this medicine out of the sight and reach of children.
- Do not store above 25ºC. Store in the original package in order to protect from moisture.
- Do not use this medicine after the expiry date which is stated on the blister and carton. 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 Lansoprazole gastro-resistant capsules contain
- The active substance is 15 mg or 30 mg of lansoprazole.
- The other ingredients are:

Capsule content: Sugar spheres (sucrose and maize starch), Sodium laurisulfate, Meglumine, Mannitol (E421), Hypromellose, Macrogol, 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 gastro-resistant capsules look like and contents of the pack
- Lansoprazole 15 mg gastro-resistant capsules are opaque yellow cap and body capsules. Each capsule contains white or almost white spherical microgranules.

- Lansoprazole 30 mg gastro-resistant capsules are opaque white cap and body capsules. Each capsule contains white or almost white spherical microgranules.

These gastro-resistant capsules are available in blister packs containing 7, 14, 28, 56 or 98 capsules. Not all pack sizes may be marketed.

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