

BYLANS 15mg GASTRO-RESISTANT CAPSULES BYLANS 30mg GASTRO-RESISTANT CAPSULES (Lansoprazole)

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT BYLANS GASTRO-RESISTANT CAPSULES ARE AND WHAT THEY ARE USED FOR

Lansoprazole belongs to a group of medicines called proton pump inhibitors. Proton pump inhibitors like lansoprazole, reduce the amount of acid that your stomach makes.

You have been given lansoprazole, because you have a condition caused by stomach acid.

Your doctor may prescribe Lansoprazole for:

- Treatment of ulcers in your stomach or duodenum
- Treatment or prevention of inflammation in your oesophagus (gullet). This is called Gastroesophageal Reflux Disease
- Treatment of infection caused by the bacteria *Helicobacter pylori* together with suitable antibiotics in the treatment of ulcers in the stomach or duodenum (eradication therapy)
- Relieving you from the unpleasant symptoms that often occur with these conditions
- Stopping these conditions coming back.
- Treatment or prevention of ulcers in stomach or duodenum in patients requiring continued NSAID treatment (NSAID treatment is used against pain or inflammation).
- Treatment of heartburn and acid regurgitation.
- Lansoprazole is sometimes given to patients whose stomach makes too much acid; this includes a condition called Zollinger-Ellison syndrome.

Your doctor may have prescribed Bylans Gastro-resistant Capsules 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. BEFORE YOU TAKE BYLANS GASTRO-RESISTANT CAPSULES

Do not take ByLans Gastro-resistant Capsules:

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

Take special care with ByLans Gastro-resistant Capsules:

It is important to talk to your doctor if you have any of the following:

- if you suffer from liver problems, the doctor may have to adjust your dosage
- treatment with Lansoprazole may lead to a slightly increased risk of gastrointestinal infections such as *Salmonella* and *Campylobacter*, contact your doctor immediately if diarrhoea occurs during the treatment with Bylans Gastro-resistant Capsules
- if your doctor has given you Bylans Gastro-resistant Capsules 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 are going to have an operation and anaesthetic (including at the dentist). Tell your doctor or dentist that you are taking Bylans Gastro-resistant Capsules
- if you take lansoprazole on a long-term basis (longer than 1 year) your doctor will probably ask to see you regularly so he can check how well you are doing. Tell your doctor if you notice any symptoms concerning your sight or if any of your other symptoms are getting worse.

Taking a proton pump inhibitor like Bylans Gastro-resistant Capsules, 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).

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.

Taking other medicines:

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription. In particular, tell your doctor if you are taking any of the following medicines:

- theophylline, which is sometimes used to treat asthma
- antacids, which are used to treat heartburn or acid regurgitation
- sucralfate, which is used for healing ulcers
- fluvoxamine, which is sometimes used to treat depression
- St John's wort (*Hypericum perforatum*), which is sometimes used to treat mild depression
- ketoconazole and itraconazole which are used to treat fungal infections
- rifampicin, which is used to treat infections
- digoxin, which is used to treat heart problems
- protease inhibitors which are used to treat viral infections
- macrolides which are used to treat bacterial infections
- tacrolimus which is used to control body immune response after organ transplantation.

Taking ByLans Gastro-resistant Capsules with food and drink

Bylans Gastro-resistant Capsules should be taken on an empty stomach (at least 30 minutes before food).

Pregnancy and Breast-feeding

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

Inform your doctor if you are pregnant, planning to become pregnant or if you are breast-feeding.

Your doctor will decide if you should take Bylans Gastro-resistant Capsules.

Driving and using machines

If you experience side effects such as dizziness, vertigo, tiredness and visual disturbances your ability to react may be decreased.

This should be taken into account when driving or using 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. 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 ByLans Gastro-resistant Capsules

Bylans 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.

3. HOW TO TAKE BYLANS GASTRO-RESISTANT CAPSULES

Swallow the capsule whole. If you find the capsules difficult to take, a drink of water at the same time might make it easier. Do not crush or chew these capsules because this will stop them from working properly.

Always take Bylans Gastro-resistant Capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

If you are taking Bylans Gastro-resistant Capsules once a day, try to take it at the same time each day. You may get best results if you take Bylans Gastro-resistant Capsules first thing in the morning.

If you are taking Bylans Gastro-resistant Capsules twice a day, you should have the first dose in the morning and the second dose in the evening.

The usual doses of Bylans Gastro-resistant Capsules for adults are given below. Sometimes your doctor will prescribe you a different dose and will tell you how long your treatment will last.

If you have liver problems your doctor may limit your dose to one capsule a day.

Healing of a stomach ulcer

The recommended dose is one 30 mg capsule every day for 4 weeks.

Prevention of an ulcer and relief of symptoms while you take an NSAID

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

Treatment of inflammation of your oesophagus (Gastroesophageal reflux disease)

The recommended dose is one 30 mg capsule a day for 4 weeks to heal your oesophagus and/or relieve symptoms.

Long term prevention of reflux oesophagitis

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

Duodenal ulcers

The recommended dose is one 30 mg capsule every day for 2 weeks. Your doctor might prescribe a further 15 mg capsule every day to prevent your ulcer coming back.

Treatment of stomach and duodenal ulcers caused by an NSAID

The recommended dose is one 30 mg capsule every day for 4 weeks.

Treatment of heartburn and acid regurgitation

The recommended dose is one 15 mg or 30 mg capsule 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.

Zollinger-Ellison syndrome (A condition where your stomach makes too much acid)

The usual dose is two 30 mg capsules every day to start with. Your doctor may then change your dose depending on how you respond to the dose that your doctor decides is best for you.

Eradication of *Helicobacter pylori* bacterium

The recommended dose is two 30 mg capsules every day for 1 week in combination with one of the following three combinations with two different antibiotics in the evening:

- amoxicillin 1 g twice daily + clarithromycin 250-500 mg twice daily
- clarithromycin 250 mg twice daily + metronidazole 400-500 mg twice daily
- amoxicillin 1 g twice daily + metronidazole 400-500 mg twice daily.

Treatment will usually be every day for 7 days.

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**.

Please read the package leaflet of the antibiotics for further information.

If you take more Bylans Gastro-resistant Capsules than you should

If you take more Bylans Gastro-resistant Capsules than you have been told to, consult your doctor or pharmacist immediately.

If you forget to take Bylans Gastro-resistant Capsules

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

If you stop taking Bylans Gastro-resistant Capsules

You should continue to take this medicine for as long as your doctor has told you. 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 product, ask your doctor or pharmacist.

Children

Bylans Gastro-resistant Capsules are not recommended for children, ask your doctor for advice.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Bylans Gastro-resistant Capsules can cause side effects, although not everybody will experience them. These are usually mild and go away when you stop taking this medicine.

The following frequency data are used in the evaluation of side effects:

Very common: affecting more than one person in 10

Common: affecting fewer than one person in 10 but more than one person in 100

Uncommon: affecting fewer than one person in 100 but more than one person in 1,000

Rare: affecting fewer than one person in 1,000 but more than one person in 10,000

Very rare: affecting fewer than one person in 10,000

Not known: cannot be calculated from the available data

Gastrointestinal disorders

Common: nausea, vomiting, diarrhoea, stomach ache, constipation, wind, dry or sore mouth or throat

Rare: fungal infections of the gullet, inflammation of the pancreas, inflammation of the tongue (glossitis), a change in the way things taste

Very rare: inflammation of the large intestine, inflammation of the mucous membrane of the mouth.

Skin and connective tissue disorders

Common: skin rash, nettle rash, itching

Rare: skin bleeding, hair loss, excessive sweating, reddening of the skin, nettle-like rash, bruising, sensitivity to light

Very rare: maplike rash on the mucous membranes/skin (Stevens-Johnson syndrome), severe skin damage (toxic epidermal necrolysis).

Not known: non-itchy, dry, ring-shaped, scaly rash (subacute cutaneous lupus erythematosus)

Nervous system disorders

Common: headaches, dizziness

Rare: restlessness, drowsiness, light-headedness, trembling, numbness/pins and needles.

Psychiatric disorders

Uncommon: depression

Rare: sleep disturbances, hallucinations, confusion

Disorders of the liver and gall bladder

Uncommon: changes in liver enzyme values

Rare: inflammation of the liver, jaundice (yellow discolouration to white of eyes or yellowing of skin).

Disorders of the kidneys and urinary tract

Rare: inflammation of the kidneys (a decrease in the volume or colour of urine).

Blood and lymphatic system disorders

Uncommon: changes in the blood count with reduction in the blood platelet count, an increase in the number of certain white blood cells (eosinophilia), a reduction in the number of all white blood cells

Rare: anaemia (reduction in a number of red blood cells)

Very rare: severe reduction in certain white blood cells (agranulocytosis), a reduced production of all blood cells.

Metabolism and nutritional disorders

Frequency not known: If you are on Bylans Gastro-resistant Capsules 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.

Disorders of the skeletal muscle, connective tissue and bones

Uncommon: muscle and joint pain, slight increase in the risk of hip, wrist or spine fractures if you take Bylans Gastro-resistant Capsules over a period of more than one year.

Eye disorders and changes in sensation of taste

Rare: visual disturbances

Hormonal disorders

Very rare: enlargement of the male breast gland, milky secretions from the nipple.

General disorders

Common: tiredness.

Uncommon: fluid retention or swelling

Rare: fever, angioedema (difficulty in breathing, swelling of lips, face, lips, mouth, difficulty to swallow, hives), loss of appetite, impotence

Very rare: allergic shock (severe fever, difficulty in breathing, swelling of lips, face, lips, mouth)

Investigations

Very rare: increased cholesterol and blood lipid values.

Although very rare the following is very serious and if you experience it you should seek urgent medical attention:

- An allergic reaction (angioedema): e.g. swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE BYLANS GASTRO-RESISTANT CAPSULES

Do not store above 30°C.

Store in the original package.

Keep out of the reach and sight of children.

Do not use Bylans Gastro-resistant Capsules after the expiry date stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not use Bylans Gastro-resistant Capsules if you notice any visible signs of deterioration.

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. FURTHER INFORMATION

What ByLans Gastro-resistant Capsules contain:

- The active substance is lansoprazole.
- The other ingredients are sugar spheres (sucrose and maize starch), sodium starch glycolate, sodium laurilsulfate, povidone, potassium oleate, oleic acid, hypromellose, methacrylic acid - ethyl acrylate copolymer 1:1, triethyl citrate, titanium dioxide (E171), talc, hypromellose, carrageenan, potassium chloride, carnauba wax. The printing ink on the capsules contains the following additional ingredients: shellac, propylene glycol, ammonium hydroxide, potassium hydroxide, black iron oxide (E172).

What ByLans Gastro-resistant Capsules look like and contents of the pack:

- Each gastro-resistant capsule has a white cap marked with L and white body marked with 15 or 30.
- It contains white to beige gastro-resistant microgranules of 15mg or 30mg lansoprazole.
- Bylans 15mg Gastro-resistant Capsules are supplied in blisters of 28 capsules.
- Bylans 30mg Gastro-resistant Capsules are supplied in blisters of 28 capsules.

Marketing Authorisation Holder and Manufacturer:

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