Lansoprazole 15 mg and 30 mg Gastro-Resistant Capsules

Package leaflet: Information for the user

For the full text of this medicine, you should consult the Summary of Product Characteristics (SmPC) provided by the manufacturer. This summary contains the very latest information about the medicine and should be read before you take the medicine.

1. What Lansoprazole is and what it is used for

The active ingredient in Lansoprazole Gastro-resistant Capsules is lansoprazole, a drug which in your stomach prevents the release of stomach acid. This means that treatment with Lansoprazole helps to relieve symptoms associated with an excess of stomach acid and reduces the amount of acid in your stomach.

Your doctor may prescribe Lansoprazole for the following conditions:

- treatment of duodenal and gastric ulcers;
- treatment of reflux oesophagitis;
- treatment or prevention of duodenal or gastric ulcers in patients requiring prolonged treatment;
- treatment of Zollinger-Ellison Syndrome;
- treatment of infectious diarrhoea.

2. What you need to know before you take Lansoprazole

Do not take Lansoprazole:

- if you are allergic (hypersensitive) to lansoprazole or any of the other ingredients of Lansoprazole Gastro-resistant Capsules;
- if you have serious liver disease. The dose of Lansoprazole may need to be adjusted. For more information, please see “How to use Lansoprazole”;
- if you have serious kidney disease.

Tell your doctor if you:

- have serious heart disease;
- have a history of some brain disorders;
- have had a stroke or have a blood disorder;
- have or have had problems with your blood.

Tell your doctor if you are taking, have taken or are going to take any other medicines, even those bought without a prescription, including herbal medicines and vitamins. This includes over-the-counter medicines and recreational drugs that you buy without a prescription. It also includes cool-tea or pain-killers. These could change the way Lansoprazole works or increase its possible side effects.

3. How to take Lansoprazole

Swallow the capsule while you have a glass of water. If you find the capsules difficult to swallow, do not chew them. If you are in a fit condition to drive a motor vehicle or perform other tasks that demand increased concentration, you should consult your doctor before taking this medicine.

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

Taking Lansoprazole with food

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

Breastfeeding and pregnancy

If you are pregnant, breast-feeding or if there is a chance you might be pregnant your doctor or pharmacist will advise you which medicines to use or alter (or replace) the ones you are already taking.

Driving and using machines

Side effects such as dizziness, vertigo, tiredness and unusual tiredness may occur as a consequence of taking Lansoprazole. If you experience side effects like those above your ability to do these things safely is reduced.

If you are in a fit condition to drive a motor vehicle or perform other tasks that demand increased concentration, you should consult your doctor before taking this medicine.

Taking Lansoprazole with tea

Seeds the capsule while you have a glass of water. If you find the capsules difficult to swallow, do not chew them. If you are in a fit condition to drive a motor vehicle or perform other tasks that demand increased concentration, you should consult your doctor before taking this medicine.

4. Possible side effects

Some of the side effects may require medical treatment. If you have any side effect, talk to your doctor or pharmacist. This includes any possible side effects that are not listed in this leaflet. See section 4.

Side effects

1. What is Lansoprazole and what is it used for

2. What you need to know before you take Lansoprazole

3. How to take Lansoprazole

4. Possible side effects
The recommended combinations of Lansoprazole are:
- 15 mg Lansoprazole together with 250 mg clarithromycin and 1000 mg amoxicillin.
- 30 mg Lansoprazole together with 525 mg clarithromycin and 400-510 mg metronidazole.

If you are being treated for infection because of an ulcer, it’s unlikely that your ulcer will return if the infection is successfully treated. To give your microbiology the best chance of doing what it’s meant to do, your doctor decides it’s best for you.

The following side effects are common (occur in less than 1 in 100 patients):
- stomach pain, nausea
- rapid or irregular heartbeat
- unusual tiredness or weakness

The following side effects are rare (occur in less than 1 in 1000 patients):
- rash, hives, red skin eruptions (paranoidosus), trembling
- unusual bleeding
- kidney problems
- gangrene
- vomiting
- inflammation of the liver (may be seen as yellow skin or eyes)
- joint and muscle pain
- inflammation of your mouth (stomatitis)
- fatigue
- sensitivity to light
- hallucinations
- fever
- very rarely, a severe skin reaction, with swelling of the mouth or throat

The following side effects are very rare (occur in less than 1 in 10,000 patients):
- swelling of your mouth ( stomatitis)
- colitis (inflamed bowel)
- changes in test values such as sodium, cholesterol and triglyceride levels

The frequency of the following side effects is not known:
- rarely, possibly with past use in patients.

If you stop taking Lansoprazole:
- you may experience heartburn again.
- you may be more likely to develop ulcers.
- you should see your doctor if you are not sure.

If you take more Lansoprazole than you are told to:
- if you take too little, it may not work as well as it should and your symptoms may return.

If you are taking Lansoprazole:
- do not take a double dose to make up for a forgotten dose.

If you forget to take Lansoprazole:
- do not take a double dose to make up for a forgotten dose.

If you stop taking Lansoprazole:
- do not stop treatment early because your condition may not have been fully healed and may reoccur if you do not finish your course of treatment.

If you stop taking Lansoprazole:
- you may experience heartburn again.
- you may be more likely to develop ulcers.
- you should see your doctor if you are not sure.

If you have any further questions on the use of the product, ask your doctor or pharmacist.

4. Possible side effects

Use all medicines, Lansoprazole can cause side effects but not everybody gets them.

Tell your doctor immediately if you notice any of the following serious side effects, you may need urgent medical treatment:
- similar to any other medicine that you take
- symptoms of blood cancer
- symptoms of ringworm
- unusual tiredness or weakness
- symptoms of inflammation in the stomach
- symptoms of liver disease
- symptoms of fungal infection in the lungs
- symptoms of fungal infection in the skin
- symptoms of tuberculosis
- symptoms of an allergic reaction to antibiotics
- symptoms of an allergic reaction to a previous medicine
- symptoms of an allergic reaction to a previous medicine
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Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of medicines.

5. How to store Lansoprazole

Keep out of the reach of children.

Do not store Lansoprazole after the expiry date which is stated on the blister and the carton. 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.

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 contains

• The active substance is lansoprazole.

What other inactive substances are contained

• The recommended combinations of Lansoprazole are:

What Lansoprazole looks like and contents of the pack

• The tablets are yellow and the 15 mg gastro resistant capsules are white. They both contain black to white microscopy (grade) Lansoprazole 15 mg and 30 mg in 28 and 98 capsule packs and tablet packs of 14, 28, 30, 56, 98 and 168 capsules. Not all pack sizes may be marketed. Your pharmacist will dispense the number of capsules prescribed by your doctor.

Marketing Authorisation Holder:

Mylan, P.O. Box, Hortforders, DNL 171, U.K.

Manufacturer:

Generics (UK) Limited, Potter St., Hortforders, DNL 171, U.K.

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