Summary Public Assessment Report

Generics

Lansopram
Lansoprazole

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Lansoprazole hard gastro-resistant capsules 15 mg and 30 mg

This is a summary of the public assessment report (PAR) for Lansopram. It explains how Lansopram was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Lansopram.

For practical information about using Lansopram, patients should read the package leaflet or contact their doctor or pharmacist.

What is Lansopram and what is it used for?
Lansopram is a 'generic medicine'. This means that Lansopram is similar to a 'reference medicine' already authorised in the European Union (EU) called Lanzo.
Lansopram is used for:

- 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.

How does Lansopram work?
The active ingredient in Lansopram is lansoprazole, which is a proton pump inhibitor. Proton pump inhibitors reduce the amount of acid in the stomach.

How is Lansopram used?
The pharmaceutical form of Lansopram is hard gastro-resistant capsules and the route of administration is oral.

The dose of Lansopram depends on the condition. The usual doses of Lansopram for adults are given below.

Treatment of heartburn and acid regurgitation: one 15 mg or 30 mg capsule for 4 weeks.
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, the doctor may adjust the 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 Lansopram together with 250-500 mg clarithromycin and 1000 mg amoxicillin
- 30 mg Lansopram together with 250 mg clarithromycin and 400-500 mg metronidazole

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, the doctor may adjust the 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 the patient's response to Lansopram the dose that the doctor decides is best for the patient.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Lansopram have been shown in studies?
Because Lansopram is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Lanzo. Two medicines are bioequivalent when they produce the same levels of the active substance in the body. The company provided data from the published literature on lansoprazole.

What are the possible side effects of Lansopram?
Because Lansopram is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.
For the full list of restrictions, see the package leaflet.

Why is Lansopram approved?
It was concluded that, in accordance with EU requirements, Lansopram has been shown to have comparable quality and to be bioequivalent to Lanzo. Therefore, the member states involved in the procedure concluded that, as for Lanzo, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Lansopram?
A risk management plan has been developed to ensure that Lansopram is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Lansopram, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Lansopram
The marketing authorisation for Lansopram was granted on 31 January 2014.

The full PAR and the package leaflet for Lansopram can be found on the website http://mri.medagencies.org/Human/. For more information about treatment with Lansopram, read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 02-2016.