

GASTROVEX CAPSULE

Lansoprazole (30mg)

What is in this leaflet

1. What Gastrovex is used for
2. How Gastrovex works
3. Before you take Gastrovex
4. How to use Gastrovex
5. While you are using it
6. Side effects
7. Storage and Disposal of Gastrovex
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Gastrovex is used for

Your doctor may prescribe Gastrovex 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 ulcers associated infections caused by the bacteria *Helicobacter pylori* when given in combination with antibiotic therapy
- Treatment or prevention of duodenal or stomach ulcer in people requiring continued NSAID treatment (NSAID treatment is used against pain or inflammation)
- Treatment of too much acid produce in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).
- Treatment of symptomatic gastroesophageal reflux disease (GERD)

Your doctor may have prescribed Gastrovex 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.

How Gastrovex works

Gastrovex is a proton pump inhibitor which is to reduce the amount of acid that your stomach makes.

Before you take Gastrovex

- When you must not use it

- if you are allergic (hypersensitive) to lansoprazole or any of the other ingredients of Gastrovex
- if you are taking a medicine containing the active substance atazanavir (used in the treatment of human immunodeficiency virus (HIV)).

Pregnancy and lactation

Do not take Gastrovex if you are pregnant, planning to get pregnant or think you may be pregnant.

Do not take Gastrovex if you are breastfeeding. Your doctor will taking into account the benefit of breastfeeding to the child and the benefit of lansoprazole therapy to the mother. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

- Please tell your doctor
- if you have liver disease

- if diarrhoea occurs during the treatment with Gastrovex, as Gastrovex has been associated with a small increase in infectious diarrhoea.
- if you take Gastrovex on a long-term basis (longer than 1 year) your doctor will probably keep you under regular surveillance.
- Your doctor may perform or have performed an additional investigation called an endoscopy in order to diagnose your condition and/or exclude malignant disease.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Gastrovex 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)

How to use Gastrovex

- How much to use

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.

Swallow the capsule whole with a glass of water. If you find the capsules difficult to swallow, your doctor may advise on alternative ways to take your medicine. Do not crush or chew these capsules or the content of an emptied capsule because this will stop it from working properly.

- When to use it

If you are taking Gastrovex once a day, try to take it at the same time each day.

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

- How long to use it

The dose of Gastrovex depends on your condition.

The usual doses of Gastrovex 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 duodenal ulcer:

one 30 mg capsule every day for 4 weeks.

Treatment of stomach ulcer:

one 30 mg capsule every day for 8 weeks.

Treatment of inflammation in your oesophagus (reflux oesophagitis):

one 30 mg capsule every day for 4 – 8 weeks.

Treatment of acid-related dyspepsia (stomach upset and indigestion):

one 30 mg capsule every day for 2-4 weeks.

Treatment of infection of *Helicobacter pylori*:

The usual dose is one 30 mg capsule in combination with two different antibiotics in the morning and in the evening. Treatment will usually be every day for 7 days.

The recommended combinations of antibiotics are:

- 30 mg Gastrovex together with 250-500 mg clarithromycin and 1000 mg amoxicillin.

- 30 mg Gastrovex together with 250-500 mg clarithromycin and 400 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 people requiring continued

NSAID treatment: one 15-30 mg capsule every day for 4-8 weeks.

Prevention of duodenal or stomach ulcer in people 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 dosage should be adjusted according to the signs and symptoms.

Short term treatment of Symptomatic GERD & erosive esophagitis for Children 12-17 years: one 30 mg capsule every day for up to 8 weeks.

- If you forget to use it

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 use too much (overdose)

If you take more Gastrovex than you have been told to, seek for doctor advice quickly.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you. Tell all the doctors, dentists and pharmacists treating you that you are taking Gastrovex.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop treatment earlier when 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.

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Gastrovex to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of
Driving and using machines
Side effects such as dizziness, vertigo, sleepiness and visual disturbances sometimes occur while taking Gastrovex. If you experience side effects like these, you should take caution as your ability to react may be decreased. If you feel that your reactions are affected, do not drive, do not use electric tools or operate machinery.

Side effects

Like all medicines, Gastrovex can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any following side effects after taking this medicine.

- headache, dizziness
- diarrhoea, constipation, stomach pains, nausea, vomiting, wind, dry mouth or throat
- skin rash, itching
- changes in liver function test values
- tiredness
- depression
- joint or muscle pain
- fluid retention or swelling
- changes in blood cell counts

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of Gastrovex

- Storage
Keep out of the reach and sight of children.

Store below 25°C in a dry place protected from light and humidity.

Do not use Gastrovex after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.

- Disposal
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.

Product Description

- What it looks like
Gastrovex Capsule 30mg is red and white hard gelatin capsules containing white to off-white pellets printed with 'LSP 30'. It is packed in 14 or 28 capsules per box.

- Ingredients

- Active ingredient: Lansoprazole
- Inactive ingredients: lactose, maize starch, carboxy methyl cellulose calcium, L-hydroxy propyl cellulose, magnesium carbonate, mannitol, sugar, povidone, hydroxy

propyl methyl cellulose phthalate, cetyl alcohol and placebo pellets.

- MAL number
MAL08042467AC

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Product Registration Holder

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