

LANPRO GASTRO-RESISTANT CAPSULES

Lansoprazole (30 mg)

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What Lanpro is used for

Lansoprazole is used in treatment of ulcer in the duodenum, non-cancerous gastric ulcer, reflux oesophagitis and Zollinger Ellison Syndrome.

Reflux oesophagitis: It is an inflammation (body's response to injury) of esophagus (food pipe) caused by back flow of stomach acid into food pipe.

Zollinger Ellison Syndrome: It is a hyper-secretory disorder where excess amount of stomach acid is produced due to tumor present in either pancreas or duodenum.

The common complaints of these ulcers and Zollinger Ellison Syndrome are abdomen pain, bloating, nausea, in severe cases blood in feces or vomiting of blood, loss of appetite and weakness.

How Lanpro works

Lansoprazole is a medicine that belongs to a category known as proton pump inhibitor. Lansoprazole works by blocking release of stomach acid in stomach.

Before you use Lanpro

- When you must not take it

- If you are allergic to lansoprazole or to any other component of this formulation
- If you are taking a medicine containing the active substance atazanavir (medicine used in

Human Immunodeficiency Virus treatment)

- If you are pregnant or planning to become pregnant or breast feeding

- Before you start to use it

Tell your doctor if you have any of the following medical conditions:

- If you have moderate to serious liver disease
- If you have osteoporosis
- If you are due to have a specific blood test (Chromogranin A), Lanpro treatment should be stopped for at least 5 days before the blood test.
- Any other medical history you feel relevant to disclose. Your doctor will prepare some tests to exclude gastric tumour as Lanpro may mask the symptoms.

- Taking other medicines

Tell your doctor or pharmacist that you are taking any of the following medicines:

- Theophylline (used to treat asthma)
- Antacids (used to treat heartburn or acid regurgitation)
- Sucralfate (used for healing of ulcers)
- Warfarin (used to prevent blood clots, heart attacks)
- Phenytoin, carbamazepine (used to treat seizures [fits])
- Ampicillin, atazanavir, ketoconazole (used to treat infections)
- Digoxin (used to treat heart problems)
- Iron Salts

Antacids and sucralfate should not be taken within an hour of Lanpro.

How to use Lanpro

Lanpro capsule should be taken as a whole and the total daily amount should be taken as a single dose with water.

- How much to use

Lanpro capsule should be taken exactly as per the advice of your doctor. Doctor may increase or decrease the dose as per your disease condition.

The usual dose of lansoprazole is 30 mg once a day.

- When to use Lanpro

Lanpro capsule has to be taken at least 30 mins before food on same time every day.

- How long to use Lanpro

Take Lanpro capsule for the duration ranged from 2 weeks to 8 weeks until your doctor tells you to stop. Talk to your doctor if you are getting too strong or too weak effect of Lanpro.

- If you forget to use Lanpro

It is important to take Lanpro capsule regularly as directed by your doctor. If you forget to take a dose, take it as soon as you remember.

If you remember at the time of your next dose then just continue with your next dose as usual. Do not take a double dose to make up for a forgotten dose as it may increase the risk of adverse effects.

- If you use too much (overdose)

If you ingested more Lanpro than desired, call your doctor or go to the nearest hospital emergency unit immediately.

While you are using it

- Things you must do

- Take dose exactly as directed by your doctor do not skip the dosing

- Things you must not do

- Do not take overdose
- Dizziness, spinning sensation, visual disturbances and sleepiness may occur. Do not drive vehicle or engage in heavy machinery work or in other potentially hazardous

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activities where attention is required.

- *Things to be careful of*

- Allergic reactions like difficulty in breathing, swelling of the face or throat. Contact your doctor immediately and stop taking Lanpro
- Diarrhoea while using lansoprazole
- If your doctor has given you Lanpro in addition to other medicines (antibiotics) intended for the treatment of *Helicobacter pylori* infection: please also read the package leaflets of these medicines carefully

Side effects

Every medicine can cause some adverse effects and it may vary from individual to individual. After taking lansoprazole you may experience headache, constipation (hard stool), anorexia (eating disorder), feeling or being sick, dry mouth, skin rash, itching, and changes in liver function test values. The other less frequent adverse effects includes changes in blood cell counts.

If you get any adverse effects talk to your doctor. You may also experience any possible adverse effects not listed in this leaflet.

When you are taking this medicine, your doctor will want to monitor you (especially if you are taking it for long term). Hence, you should report any new and exceptional symptoms and circumstances whenever you see your doctor. Please tell your doctor promptly if you get any of the symptoms below:

- Rash (especially in areas exposed to the sun), possibly with pain in the joints.(Subacute Cutaneous Lupus Erythematosus, SCLE)
- Fever, extreme tiredness, pus/blood in urine.

- Involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate
- Fracture in the hip, wrist or spine.
- Watery stool, stomach pain and fever that do not go away.
- Anemic (pale skin, weakness, tiredness or lightheadedness), shortness of breath, a smooth tongue, nerve problems (numbness or tingling, muscle weakness and problems walking), vision loss and mental problems (depression, memory loss or behavioral changes).

a) Subacute Cutaneous Lupus Erythematosus (SCLE)
Frequency “not known”

b) Interstitial Nephritis
Kidney problems

c) Hypomagnesaemia
Frequency “not known”: Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood.

d) Fracture
Frequency “uncommon”: Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

e) Clostridium Difficile Diarrhea
Severe diarrhoea which may be caused by an infection (Clostridium difficile) in your intestines.

f) Fundic Gland Polyps (Benign)
Frequency “Common”: Benign polyps in the stomach

g) Vitamin B12 Deficiency
Proton pump inhibitors may cause vitamin B12 deficiency.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website npra.moh.gov.my (Public->Reporting

Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage & disposal of Lanpro

- *Storage*

Lanpro capsule should be Store below 30°C, protect it from light and moisture and keep Lanpro capsule out of reach of children.

- *Disposal*

Dispose of Lanpro capsule if any remaining after discussing with your pharmacist. Do not throw it in dustbin or elsewhere. Do not keep Lanpro capsule after expiry date.

Product description

- *What it looks like*

White to off-white spherical pellets in capsule with light blue cap and opaque with white body with 'LANPRO' printed in black on body and cap.

- *Ingredients*

- Active ingredient: Lansoprazole
- Inactive ingredient: Mannitol, Hydroxy Propyl Methyl Cellulose, Methacrylic acid-copolymer dispersion, Light Magnesium Carbonate, Disodium hydrogen ortho phosphate, Diethyl phthalate, Sucrose, Titanium dioxide, Povidone, Calcium CMC, Talc, Sugar Spheres, Tween-80, Sodium Hydroxide, Hard Gelatin capsule shell

- *MAL number:*MAL10033131AZ

Manufacturer

Unichem Laboratories Ltd.
15, 16, 17A, 17 & 18, Pilerne Ind. Estate, Pilerne, Bardez , Goa 403 511 India.

Product Registration Holder

Healol Pharmaceuticals Sdn Bhd.
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