

NEW ZEALAND CONSUMER MEDICINE INFORMATION

LANZOL RELIEF

Lansoprazole Modified Release Capsules 15mg & 30mg



What is in this leaflet

This leaflet answers some common questions about LANZOL RELIEF.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

Take LANZOL RELIEF as directed and follow the advice given in the leaflet.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking LANZOL RELIEF against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What LANZOL RELIEF is taken for

LANZOL RELIEF contains the active ingredient lansoprazole. It belongs to a group of medicines called Proton Pump Inhibitors or PPIs.

Ulcers

LANZOL RELIEF is taken to treat or help heal peptic ulcers of the stomach and duodenum. These can be caused in part by too much acid being made in the stomach. LANZOL RELIEF is also used to help stop duodenal ulcers re-occurring.

Reflux Oesophagitis

LANZOL RELIEF is used to treat reflux oesophagitis or reflux

disease. This is caused by "washing back" (reflux) of food and acid from the stomach into the food pipe, also known as the oesophagus.

Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.

Helicobacter pylori

LANZOL RELIEF can also be used in combination with certain antibiotics to help eliminate *H. pylori* infections in certain people with ulcers or chronic gastritis. *H. pylori* is a bacteria which is associated with the development of ulcers.

LANZOL RELIEF works by decreasing the amount of acid the stomach makes to give relief from the symptoms and allow healing to take place.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive and is available only with a doctor's prescription.

There is insufficient information to recommend use of this medicine in children.

Before you take LANZOL RELIEF

When you must not take it:

Do not take LANZOL RELIEF if you have an allergy to:

- lansoprazole or other proton pump inhibitors
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not give this medicine to a child under the age of 12 years. Safety and effectiveness in children younger than 12 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it:

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding. Your doctor can discuss with you the risks and benefits involved.

Your doctor can discuss with you the risks and benefits involved with taking LANZOL RELIEF.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and LANZOL RELIEF **may** interfere with each other. These include:

- theophylline, used to treat asthma
- Vitamin B12 (Hydroxocobalamin), used to prevent and treat anaemia associated with vitamin B12 deficiency.
- Tacrolimus, an immunosuppressive medicine.
- carbamazepine a medicine used to treat epilepsy
- warfarin a medicine used to thin the blood and prevent blood clots
- Atazanavir and nelfinavir, medicines used to treat HIV/AIDS.
- phenytoin used to treat seizures or heart rhythm disorders
- ketoconazole, itraconazole and some other antibiotics which are used to treat infections
- iron medicines for anaemia which is low iron levels in the blood
- digoxin a heart medicine
- methotrexate, a medicine used to treat arthritis or cancer
- Antacid, a medicine used to neutralise the stomach pH
- sucralfate, another type of gastrointestinal medication. Lansoprazole should be taken at least 1 hour before taking sucralfate if both these medicines are being taken.

These medicines may or may not be affected by LANZOL RELIEF or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take LANZOL RELIEF

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box label ask your doctor or pharmacist for help.

How much to take

Reflux oesophagitis:

Dose: 30 mg lansoprazole once daily for 4 weeks. If you are not fully healed within this time your doctor will prescribe a second 4-week course of LANZOL RELIEF. To prevent relapse, your doctor may suggest a maintenance dose of 15 or 30 mg daily. Your doctor will tell you the duration of treatment. Do not interrupt or stop your treatment.

Duodenal ulcer:

Dose: 30 mg of lansoprazole once daily for 4 weeks. To prevent relapse, your doctor may suggest a maintenance dose of 15 mg once daily. Your doctor will tell you the duration of treatment. Do not interrupt or stop your treatment.

Gastric ulcer:

Dose: 30 mg of lansoprazole once daily for 8 weeks.

Eradication of *H. pylori*:

Your doctor will try to eradicate the infection with one of the following combinations of treatment:

- 30 mg lansoprazole twice daily
- and two of the following antibiotics - amoxicillin 1 g twice daily, metronidazole 400 mg twice daily or clarithromycin 250 mg twice daily.

Liver Impairment:

You doctor may reduce the daily dose of lansoprazole if you have moderate to severe liver disease as your body takes longer to remove the medicine from your body.

How to take it

Swallow LANZOL RELIEF capsules whole with a full glass of water or other liquid.

Do not chew the capsules.

When to take it

Take your LANZOL RELIEF at about the same time every day. This will help you remember when to take the capsules.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It is preferable to take this medicine on an empty stomach first thing in the morning.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

If you forget to take it

Take it as soon as you remember, and then go back to taking it as you would normally. If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking LANZOL RELIEF

Things you must do

Take LANZOL RELIEF exactly as your doctor has prescribed.

Tell your doctor if you become pregnant while taking LANZOL RELIEF. LANZOL RELIEF may affect your developing baby if you take it during pregnancy.

Also tell your doctor if you are breastfeeding or intend to breast feed. LANZOL RELIEF passes into

breast milk and could affect your baby.

If you are prescribed any new medicine, remind your doctor and pharmacist that you are taking LANZOL RELIEF.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some blood tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take LANZOL RELIEF to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor. If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

Things to be careful of

LANZOL RELIEF may cause dizziness or light-headedness in some people, especially after the first dose. **Make sure that you know how you react to LANZOL RELIEF before you drive a car, operate machinery, or do anything else that could be**

dangerous if you have dizziness, blurred vision or headache.

If you drink alcohol, dizziness or light-headedness may be worse.

Things that may help your condition

Some self help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures and for more information.

- **Alcohol** - your doctor may advise you to limit your alcohol intake.
- **Aspirin and many other medications used to treat arthritis/ period pain/ headaches** - these medicines may irritate the stomach and may make your condition worse. Your doctor or pharmacist may suggest other medicines you can take.
- **Caffeine** - your doctor may advise you to limit the number of drinks which contain caffeine, such as coffee, tea, cocoa and cola drinks, because they contain ingredients that may irritate your stomach.
- **Eating habits** - eat smaller, more frequent meals. Eat slowly and chew your food carefully. Try not to rush at meal times.
- **Smoking** - your doctor may advise you to stop smoking or at least cut down.
- **Weight** - your doctor may suggest losing some weight to help your condition.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much LANZOL RELIEF.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking LANZOL RELIEF, even if you do not think that the problems are connected with the medicine or they are not listed in this leaflet.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the more serious side effects.

If you are on LANZOL RELIEF 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 (muscle spasms delirium, seizures or muscle twitching), disorientation, convulsions, dizziness, increased or irregular 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.

Taking a proton pump inhibitor medicine like LANZOL RELIEF, 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 a corticosteroid medicine (which can increase the risk of osteoporosis).

Tell your doctor if you have any of the following and they worry you:

- headache
- diarrhoea or constipation
- stomach pain
- nausea
- indigestion
- vomiting
- dizziness
- vertigo
- flatulence (wind)
- tiredness
- skin rashes
- joint aches, pains or stiffness
- upper respiratory infections (cough, cold, sore throat or sinus)
- urinary tract infections
- hives and itching
- hair thinning
- sensitivity to light
- dry mouth or throat
- taste disturbances.

These side effects are usually mild and go away.

Tell your doctor as soon as possible if you notice any of the following:

- depression
- swelling of hands, ankles or feet
- tingling or pricking (pins and needles)
- numbness of hands and feet
- blurred vision
- confusion
- hallucinations
- shaking, tremor or seizure
- spasm or twitching of the muscles, particularly in the face, feet and hands (tetany)
- bruising
- bleeding under the skin
- breast enlargement and impotence (erectile dysfunction) in men with long term use.

Rarely, more serious side effects may occur. If any of the following happen, stop taking LANZOL RELIEF and tell your doctor immediately or go to the Accident

and Emergency at your nearest hospital:

- yellowing of the skin or eyes
- liver disease with nausea, vomiting, loss of appetite, fever, itching and dark coloured urine
- kidney disease
- sudden signs of allergy such as swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- flu-like symptoms followed by painful rash and blisters
- blistering and peeling skin
- widespread non-scarring rash that is sensitive to light
- red, itchy blistering spots
- red or purple flat pinhead spots under skin
- red scaly patches or ring-shaped lesions on chest, neck and upper back
- change in the way the heart beats, or change in the speed or rhythm of the heart beat.

The above side effects are serious and also rare. If you experience any of these side effects you should seek urgent medical attention.

Tell your doctor if you experience anything else that causes you pain or discomfort.

As natural acid in the stomach helps to kill bacteria, the lowering of acid by acid-reducing drugs such as LANZOL RELIEF may make some people have certain stomach infections. **If you suffer from severe persistent diarrhoea and/or vomiting when taking LANZOL RELIEF, tell your doctor.**

Other problems are more likely to arise from the ulcer itself rather than the treatment. For this reason, contact your doctor immediately if you notice any of the following:

- Pain or indigestion occurring during treatment with LANZOL RELIEF
- You begin to vomit blood or food

- You pass black (blood-stained) motions

Do not be alarmed by this list of possible side effects. They do not occur often and you are unlikely to experience any of them.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking LANZOL RELIEF.

After taking LANZOL RELIEF

Storage

Keep your tablets in the pack until it is time to take them.

If you take the capsules out of the pack they may not keep well.

Keep your capsules in a cool dry place where the temperature stays below 25°C.

Do not store LANZOL RELIEF or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What LANZOL RELIEF looks like

LANZOL RELIEF 15 mg capsules are hard gelatin capsules with a

green opaque cap and body, containing white to off-white coloured pellets and imprinted with 'MYLAN' over '8015' on both cap and body in black ink.

LANZOL RELIEF 30 mg capsules are hard gelatin capsules with a pink opaque cap and body, containing white to off-white coloured pellets and imprinted with 'MYLAN' over '8030' on both cap and body in black ink.

Ingredients

Active ingredient:

LANZOL RELIEF capsule contains either 15 mg or 30 mg lansoprazole as the active ingredient.

Inactive ingredients:

LANZOL RELIEF capsule also contains:

- sugar spheres,
- heavy magnesium carbonate,
- sucrose,
- corn starch,
- hydroxypropyl cellulose,
- methacrylic acid-ethyl acetate copolymer,
- talc,
- polyethylene glycol,
- titanium dioxide,
- polysorbate 80
- colloidal anhydrous silica.

The hard gelatin capsules are made of:

- gelatin,
- titanium dioxide and
- are imprinted with black Tek Print Ink SW-9009.

Additionally, the 15 mg gelatin capsules contain the following permitted colourants, FD & C Green # 3 and FD & C Red # 40 and the 30 mg gelatin capsules FD & C Blue # 1 and FD & C Red # 3.

Contains phenylalanine, sulfites and sugars.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

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Date of Preparation

08 January 2024
(Based on the datasheet dated 08 January 2024)