

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about LANZOPRAN.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from <https://www.ebs.tga.gov.au/> and may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking LANZOPRAN against the benefits it is expected to 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 Lanzopran is used for

The name of your medicine is **LANZOPRAN**.

LANZOPRAN contains lansoprazole as active ingredient. Lansoprazole belongs to a group of medicines called proton pump inhibitors (PPIs). Lansoprazole works by decreasing the amount of acid the stomach makes, to give relief from the symptoms and allow healing to take place.

Reflux Oesophagitis (inflammation of oesophagus):

LANZOPRAN is used to treat the symptoms of reflux oesophagitis or reflux disease in adults and in children from 1 to 17 years of age. This can be caused by backflow (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 heart burn.

Peptic Ulcers (Ulcers of stomach or duodenum):

LANZOPRAN is used to treat peptic ulcers in adults. Depending on the position of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum, which is the tube leading out of the stomach. These can be caused in part by too much acid being made in the stomach. LANZOPRAN is also used to stop duodenal ulcers from coming back.

LANZOPRAN is also used for treatment of infections caused by the bacteria *Helicobacter pylori* when given in combination with antibiotic therapy.

LANZOPRAN is also used for the treatment of heartburn and acid regurgitation.

This medicine is available only with a doctor's prescription.

Before you take Lanzopran

When you must not take it

- **Do not take LANZOPRAN if you are allergic to lansoprazole**, any medicines containing a proton-pump inhibitor or

any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include skin rash, itchiness or hives, shortness of breath, wheezing or difficulty breathing, swelling of the tongue, lips, face or other parts of the body.

- **Do not take LANZOPRAN if you have severe problems with your liver.**
- **Do not take LANZOPRAN if you are already taking the medicine atazanavir.**
Atazanavir is used to treat HIV infection. If it is taken at the same time as LANZOPRAN, it won't be absorbed properly and will be less effective in treating HIV infection.
- **Do not take LANZOPRAN after the expiry date printed on the pack.**
If you take it after the expiry date has passed, it may not work as well.
- **Do not take LANZOPRAN if the capsules do not look quite right.**
- **Do not take LANZOPRAN if the packaging is torn or shows signs of tampering.**

If you are not sure whether you should start taking LANZOPRAN, talk to your doctor or pharmacist.

Before you start to take it

You must tell your doctor if you:

- **Have any allergies to:** any medicines, foods, dyes or preservative.
 - **Are pregnant or intend to become pregnant:** your doctor will discuss the possible risks and benefits of taking LANZOPRAN.
 - **Are breast-feeding currently or intend to breast-feed:** lactating women should not breast-feed while taking LANZOPRAN.
 - **Have or have had any medical conditions including the following:**
 - problems with your kidney(s) or liver
 - inflammation of the bowel
 - an abnormal growth (tumour) in stomach.
- Have problems with digestion, or have an intolerance to:
- Fructose
 - Glucose
 - Galactose
 - Lactose
 - Sucrose

If you have not told your doctor about any of the above, tell them before you take LANZOPRAN.

Taking other medicines

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

Some medicines may interfere with LANZOPRAN. These include:

- Theophylline, used to treat asthma
- Carbamazepine and phenytoin used to treat fits (seizures)
- Warfarin, used to prevent blood clot
- Oral contraceptive

- Sucralfate (used to treat stomach ulcers) and antacids (used to treat heartburn). **LANZOPRAN** should be taken at least an hour prior sucralfate or antacid administration.
- Ampicillin esters and clarithromycin antibiotic
- Ketoconazole used to treat fungal infection
- Iron salt preparation
- Digoxin for cardiac complication
- Tacrolimus used in transplant patients to reduce organ rejection
- Atazanavir, nelfinavir or other medicines used to treat HIV infection
- Methotrexate used to treat some cancers.

These medicines may be affected by LANZOPRAN or they may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

How to use Lanzopran

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

This may differ from the information contained in this leaflet.

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

When to take it

Take LANZOPRAN in the morning before food.

How much to take

Take one LANZOPRAN capsule each day, unless your doctor has told you otherwise.

Adults

The dose to be taken depends on what your condition is and how long you require treatment. It may vary from 15 mg to 30 mg per day.

Children and Adolescents (1-17 years old)

The recommended dose depends on the weight of the child or adolescent.

For those weighing 30 kg or less, the usual dose is one LANZOPRAN 15 mg capsule daily.

For those weighing over 30 kg, the usual dose is one LANZOPRAN 30 mg capsule daily.

How long to take it

Continue taking the capsules for as long as your doctor tells you. Do not stop taking it unless your doctor tells you to, even if you feel better.

In most patients, lansoprazole relieves symptoms rapidly and healing is usually complete within 4 weeks, although the pain and discomfort caused by the ulcer or reflux may go away well before all the prescribed LANZOPRAN capsules have been finished.

Although lansoprazole heals ulcers very successfully, it may not prevent them from coming back at a later date. Your doctor may want you to keep taking LANZOPRAN long-term to prevent the condition from recurring. However, lansoprazole is only recommended for short-term use (8 to 12 weeks) in children.

Tell your doctor if your symptoms return.
You may need further treatment.

How to take it

The capsule should be swallowed whole with plenty of water. Do not crush or chew.

If you have difficulty swallowing LANZOPRAN, you can open a capsule and administer as follows:

Sprinkle intact granules on one tablespoon of apple sauce, strained pears, cottage cheese or yoghurt and swallow immediately. The capsules may also be emptied into a small volume of either apple juice, orange juice or tomato juice. Mix briefly and swallowed immediately.

To ensure complete delivery of the dose, the glass should be rinsed with two or more volumes of juice and the contents swallowed immediately.

Do not use other foods or liquids to swallow the granules because they have not been tested for use with LANZOPRAN.

If you have a nasogastric tube in place:
LANZOPRAN may be given by a doctor or nurse by mixing the intact granules from the capsule with 40 mL of apple juice and injecting the mixture through the tube into the stomach. The tube is then flushed with more apple juice to clear it.

If you forget to take it

- Take your dose as soon as you remember, and then continue to take 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 you missed. This may increase the chance of you getting an unwanted side effect.

If you have missed more than one dose, or are not sure what to do, check with your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Tel. 131126) for advice, or go to Accident & Emergency at your nearest hospital.

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

Keep these numbers handy in case of an emergency.

While you are using Lanzopran

Things you must do

Use LANZOPRAN exactly as your doctor has prescribed.

Tell your doctor if you become pregnant while you are taking LANZOPRAN.

Tell all doctors, dentist and pharmacists who are treating you that you are taking LANZOPRAN.

Tell your doctor that you are taking LANZOPRAN before any blood tests. This medicine may interfere with the results of certain tests.

Things you must not do

Do not give LANZOPRAN to anyone else, even if their symptoms seem similar or they have the same condition as you. Your doctor has prescribed it for you and your condition only.

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

Do not stop taking LANZOPRAN, or lower the dosage, even if you are feeling better, 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

Be careful driving or operating machinery until you know how LANZOPRAN affects you.

LANZOPRAN generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, LANZOPRAN may cause dizziness or light-headedness in some people.

Make sure you know how you react to LANZOPRAN before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed.

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 medicines used to treat arthritis, period pain or 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using LANZOPRAN.

LANZOPRAN helps most people with ulcers or reflux, but it may have unwanted side effects in some.

All medicines 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 side effects.

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

Stomach or bowel problems such as:

- diarrhoea, constipation
- indigestion, nausea (feeling sick), vomiting (being sick)
- flatulence or wind

- abdominal or stomach pain
- Tell your doctor if you suffer from severe persistent diarrhoea and/or vomiting when taking LANZOPRAN.**
The natural acid in your stomach helps kill bacteria. Taking medicines (such as lansoprazole) that reduce acid may result in stomach infections in some people.

Difficulty in thinking or working due to:

- headache
- fatigue (tiredness)
- light-headedness, feeling like you may faint
- generally feeling unwell
- joint or muscle aches or pain
- feeling depressed or confused
- having hallucinations

Changes to appearance such as:

- skin rashes
- hives or itchy skin
- thinning hair
- breast enlargement and impotence in men (with long-term use)

Signs of infection such as:

- coughs, colds, sore throats, or sinuses indicating an upper respiratory tract infection
- dry or sore mouth or throat
- frequent and painful passing of urine indicating urinary tract infection

Changes in sight, hearing, taste or touch including:

- taste disturbances
- tingling or numbness of hands and feet
- blurred vision
- increased sensitivity to sunlight

These are more common side effects of lansoprazole.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- red, itchy blistering spots, especially if it appears in areas of the skin that are exposed to the sun and is accompanied by joint pain
- pain in the kidney region
- bruising or bleeding more easily than usual, bleeding under the skin or red or purple flat pinhead spots under the skin
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- watery or severe diarrhoea with stomach and bowel problem [#]
- yellowing of the skin or eyes, especially if accompanied by fever, fatigue, loss of appetite, dark coloured urine or light coloured bowel movements[#]
[#]These side effects may occur when LANZOPRAN is used in combination with antibiotics for *H. pylori* infection.
- symptoms of sunburn such as redness, itching or blistering
- Severe blisters and bleeding in the lips, eyes, mouth, nose or genitals (Stevens-Johnson syndrome)
- sudden signs of allergy such as rash, itching, or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing
- frequent infections such as fever, severe chills, sore throat or mouth ulcers

- cramping of the muscles in your hands or feet
- irregular heartbeat
- fits or seizures.

These are serious to very serious side effects. You may need urgent medical attention. These side effects are rare.

Other side effects not listed above may occur in some patients. Tell your doctor if you notice anything that make you feel unwell when you are taking, or soon after you have finished taking, **LANZOPRAN**.

For this reason, contact your doctor immediately if you notice any of the following:

- pain or indigestion occurring during treatment with **LANZOPRAN**
- you begin to vomit blood or food
- you pass black (blood-stained) motions

Ask your doctor or pharmacist if you do not understand anything in this list. Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Lanzopran

Storage

Keep **LANZOPRAN** in the original pack until it is time to take them.

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

Keep **LANZOPRAN** in a cool, dry place where the temperature is below 25°C.

Do not store **LANZOPRAN** or any medicine in the bathroom or near a sink. Do not leave medicines in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep **LANZOPRAN** where children cannot reach it.

A locked cupboard at least one and a half metres (1.5 m) above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking LANZOPRAN, or your medicine has passed its expiry date, ask your pharmacist what to do with any capsules which may be left over.

Product description

What LANZOPRAN looks like

LANZOPRAN 30 mg - Purple cap/lavender body, self-locked hard gelatin capsules of size '1' imprinted with 'L 30' on both cap and body, containing white to off-white pellets.

LANZOPRAN 30 mg is available in blister packs of 28 capsules.

Ingredients

LANZOPRAN does not contain gluten and lactose.

Active ingredient:

Each **LANZOPRAN** contains 30 mg of lansoprazole as active ingredient.

Inactive ingredients:

sugar spheres (sugar, starch), hypromellose, purified talc, titanium dioxide, macrogol 300, colloidal anhydrous silica, methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30%, OPACODE monogramming ink S-1-277002 black. The capsule shells contain gelatin and titanium dioxide, and the

colourants indigo carmine CI73015 and carmoisine CI14720 (30 mg capsule). The capsules are imprinted with OPACODE S-1-277002 black ink.

Australian Registration Numbers

LANZOPRAN 30 mg capsule - AUST R 159343

Sponsor

LANZOPRAN capsules are supplied in Australia by:

Sun Pharma ANZ Pty Ltd

12 Waterloo Road

Macquarie Park, NSW 2113

Email:

customerservice.aus@sunpharma.com

Tel no. 1800 726 229

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