

Noumed Lansoprazole

lansoprazole

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about NOUMED LANSOPRAZOLE. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking NOUMED LANSOPRAZOLE 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 this medicine is used for

The name of your medicine is NOUMED LANSOPRAZOLE.

It contains lansoprazole as active ingredient. Lansoprazole belongs to a group of medicines called proton pump inhibitors (PPIs). It 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): NOUMED LANSOPRAZOLE 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): NOUMED

LANSOPRAZOLE 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.

NOUMED LANSOPRAZOLE is also used to stop duodenal ulcers from coming back.

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

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

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

Before you take this medicine

When you must not take it

Do not take NOUMED LANSOPRAZOLE if you have an allergy to:

- any medicine containing lansoprazole,
- any medicines containing a proton-pump inhibitor, or

- 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
- add any other specific reactions listed in the PI.

Do not take NOUMED LANSOPRAZOLE if:

- you have severe problems with your liver
- you are taking atazanavir, used to treat HIV infection.

Do not take this medicine:

- after the expiry date printed on the pack. If you take it after the expiry date has passed, it may not work as well.
- if the capsules do not look quite right.
- if the packaging is torn or shows signs of tampering.

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

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 have or have had any of the following medical conditions:

- problems with your kidney(s) or liver
- inflammation of the bowel

- an abnormal growth (tumour) in stomach.

You have problems with digestion or have an intolerance to:

- Fructose
- Glucose
- Galactose
- Lactose
- Sucrose

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

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

Lactating women should not breastfeed while taking NOUMED LANSOPRAZOLE.

If you have not told your doctor about any of the above, tell him/her before you start taking NOUMED LANSOPRAZOLE.

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 NOUMED LANSOPRAZOLE may interfere with each other. These include:

- Theophylline, used to treat asthma
- Carbamazepine and phenytoin used to treat fits (seizures)
- Warfarin, used to prevent blood clot
- Tacrolimus and mycophenolate, used in transplant patients to reduce organ rejection
- Fluvoxamine, used to treat major depression or Obsessive-Compulsive Disorder
- Oral contraceptive
- Sucralfate (use to treat stomach ulcers) and antacids (used to treat heartburn). NOUMED LANSOPRAZOLE 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
- Methotrexate, used to treat some cancers
- Atazanavir, nelfinavir or other medicines used to treat HIV infection.

These medicines may be affected by NOUMED LANSOPRAZOLE 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 this medicine

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

They may differ from the information contained in this leaflet.

How much to take

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

Adults

The usual dose is 30 mg a day. It may vary from 15 mg to 30 mg per day depending on your condition.

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 15 mg capsule daily.

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

How to take it

The capsule should be swallowed whole with plenty of water.

Do not crush or chew.

If you have difficulty swallowing NOUMED LANSOPRAZOLE, you can open a capsule and take 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 NOUMED LANSOPRAZOLE.**

If you have a nasogastric tube in place:

- NOUMED LANSOPRAZOLE 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.

When to take it

Take NOUMED LANSOPRAZOLE in the morning before food.

Take your medicine on an empty stomach, for example, 1 hour before food or 2 hours after food.

Food can interfere with the absorption of this medicine.

If you need to take an antacid, take it at least 1 hour after your dose of NOUMED LANSOPRAZOLE.

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 NOUMED LANSOPRAZOLE 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 NOUMED LANSOPRAZOLE 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.

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

(telephone 13 11 26) 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 NOUMED LANSOPRAZOLE. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using this medicine

Things you must do

Use NOUMED LANSOPRAZOLE exactly as your doctor has prescribed.

Tell your doctor if you become pregnant while you are taking NOUMED LANSOPRAZOLE.

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

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

Things you must not do

Do not give NOUMED LANSOPRAZOLE 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 NOUMED LANSOPRAZOLE to treat any other complaints unless your doctor tells you to.

Do not stop taking NOUMED LANSOPRAZOLE, 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 NOUMED LANSOPRAZOLE affects you.

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

Make sure you know how you react to NOUMED LANSOPRAZOLE before you do drive a car, operate machinery, or 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 would be helpful for 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. Eat your meals well before bedtime

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 taking NOUMED LANSOPRAZOLE.

This medicine helps most people with ulcers or reflux, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention 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 NOUMED LANSOPRAZOLE.

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
- dizziness
- 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:

- 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 NOUMED LANSOPRAZOLE is used in combination with antibiotics for H. pylori infection.

- symptoms of sunburn such as redness, itching or blistering
- 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

- 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.

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 NOUMED LANSOPRAZOLE
- You begin to vomit blood or food
- You pass black (blood-stained) motions.

Tell your doctor if you notice anything that make you feel unwell when you are taking, or soon after you have finished taking, NOUMED LANSOPRAZOLE.

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 this medicine

Storage

Keep NOUMED LANSOPRAZOLE until it is time to take them.

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

Keep this medicine in a cool dry place where the temperature stays below 25°C.

Do not store this medicine 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.

The capsules are imprinted with OPACODE S-1-277002 black ink.

Australian Registration Numbers

NOUMED LANSOPRAZOLE
30 mg capsule – AUST R 324704

Sponsor

Avallon Pharmaceuticals Pty Ltd
Level 5, 7 Eden Park Drive
Macquarie Park NSW 2113
Australia

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Product description

What it looks like

NOUMED LANSOPRAZOLE
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.

Available in blister packs of 28 capsules.

Ingredients

NOUMED LANSOPRAZOLE
contains 30 mg of lansoprazole as the 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, titanium dioxide and the colourants indigo carmine CI73015 and carmoisine CI14720.