

APO-Lansoprazole Capsules

Contains the active ingredient, Lansoprazole

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

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

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Lansoprazole. It contains the active ingredient lansoprazole.

In adults it is used to treat:

- reflux oesophagitis
- peptic ulcers
- Helicobacter pylori infection in patients with peptic ulcer or chronic gastritis
- reflux-like and/or ulcer-like symptoms associated with acid-related dyspepsia

In children aged 1-17 years of age it is used to treat:

- gastro-oesophageal reflux disease, including all grades of oesophagitis
- erosive oesophagitis

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

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

How it works

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.

There is no evidence that this medicine is addictive.

Before you take this medicine

Do not take this medicine if:

- **You have or have had any of the following:**
 - severe liver disease.
- **You are taking atazanavir, a medicine used to treat HIV.**
- **You are hypersensitive to, or have had an allergic reaction to, lansoprazole, other proton pump inhibitors or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**

- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to use it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - kidney or liver problems
 - a tumour in the stomach region
 - osteoporosis
 - low magnesium levels
 - fructose intolerance, glucose galactose malabsorption or sucrose-isomaltase insufficiency.
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with lansoprazole. These include:

- theophylline, used to treat asthma
- carbamazepine and phenytoin used to treat seizures (fits)
- warfarin, used to prevent blood clot

- oral contraceptives
- sucralfate (used to treat stomach ulcers) and antacids (used to treat heartburn). Lansoprazole should be taken at least an hour prior to taking sucralfate or an antacid
- ampicillin esters, used in some antibiotics
- ketoconazole, itraconazole, used to treat fungal infections
- iron preparations
- digoxin, used to treat heart conditions
- tacrolimus or mycophenolate used in transplant patients to reduce organ rejection
- methotrexate, used in rheumatoid arthritis and some cancers to control immune response
- atazanavir and others that require an acidic pH to be effective to treat HIV
- fluvoxamine, used to treat depression and anxiety
- rifampicin, an antibiotic
- St John's wort, a herbal medicine.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with lansoprazole.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take.

This will depend on your condition and whether you are taking any other medicines.

For children, this will also depend on their weight.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

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

If you have difficulty swallowing this medicine, the capsule can be opened and taken as follows:

- sprinkle the intact granules on one tablespoon of apple sauce, strained pears, cottage cheese or yoghurt and swallow immediately
- or sprinkle the intact granules 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 this medicine.

If you have a nasogastric tube in place, this medicine 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 this medicine in the morning before food.

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

How long to take it

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

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

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

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

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

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

Lansoprazole may cause dizziness in some people.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking lansoprazole or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following.

Stomach or bowel problems such as:

- diarrhoea, constipation
- indigestion
- nausea (feeling sick), vomiting
- flatulence or wind
- abdominal or stomach pain .

Tell your doctor if you suffer from severe persistent diarrhoea and/or vomiting when taking 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
- fatigue (tiredness)
- dizziness
- generally feeling unwell
- joint or muscle aches or pain
- feeling depressed, confused or having hallucinations.

Changes to your appearance such as:

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

Signs of infection such as:

- cough, cold, sore throat or sinus
- dry or sore mouth or throat
- frequent and painful passing of urine.

Changes in sight, hearing, taste or touch including:

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

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

These may be serious side effects and you may need medical attention:

- pain or indigestion
- vomiting blood or food
- passing black (blood-stained) motions.

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 problems
- yellowing of the skin or eyes, especially if accompanied by fever, fatigue, loss of appetite, dark coloured urine or light coloured bowel movements
- symptoms of sunburn such as redness, itching or blistering
- cramping of the muscles in your hands or feet
- irregular heartbeat
- fits or seizures
- hallucinations.

These are very serious side effects and you may need urgent medical attention or hospitalisation.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to lansoprazole, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original pack until it is time to take them.

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

Keep your medicine in a cool, dry place where the temperature will stay below 25°C.

Do not store your medicine, 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 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 it has passed its expiry date, ask your pharmacist what to do with any capsules which may be left over.

Product description

What APO-Lansoprazole looks like

APO-Lansoprazole 15 mg

Yellow cap/yellow body, self-locked hard gelatin capsules of size '3' imprinted with 'L 15' on both cap and body, containing white to off-white pellets.

APO-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.

APO-Lansoprazole 15 mg and 30 mg are available in blister packs of 28 capsules.

Ingredients

Each APO-Lansoprazole Enteric Capsules contains 15 mg or 30 mg of lansoprazole as active ingredient.

It also contains the following inactive ingredients:

- sucrose
- starch
- talc
- hypromellose
- titanium dioxide
- methacrylic acid-ethylacrylate copolymer
- macrogol 300
- colloidal anhydrous silica
- gelatin

The 15 mg enteric capsule also contains the below colourants:

- yellow iron oxide CI77492
- quinoline yellow CI47005.

The 30 mg capsule contains the colourants:

- indigo carmine CI73015
- carmoisine CI14720.

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

This medicine does not contain gluten and lactose.

Australian Registration Numbers

APO-Lansoprazole 15 mg enteric capsule: AUST R 159350

APO-Lansoprazole 30 mg enteric capsule: AUST R 159345

Sponsor

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