

APO-Lansoprazole ODT

Lansoprazole

Consumer Medicine Information

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

What is in this leaflet

This leaflet answers some common questions about APO-Lansoprazole ODT. 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 this medicine 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

Peptic Ulcers

APO-Lansoprazole ODT 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.

Too much acid being made in the stomach can cause these ulcers. APO-Lansoprazole ODT is also used to help stop duodenal ulcers from coming back.

Reflux Oesophagitis

APO-Lansoprazole ODT is used to treat the symptoms of reflux oesophagitis or reflux disease in adults and in children from 6 to 17 years of age.

This can be caused by backflow (reflux) of food and acid from the stomach into the food pipe or gullet, also known as the oesophagus.

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

Heartburn and Stomach Pain Associated with Reflux or Peptic Ulcer

APO-Lansoprazole ODT is used for the short-term treatment of heartburn and peptic ulcer symptoms in adults.

Peptic Ulcers Associated with Helicobacter Pylori Infection

Most people who have a peptic ulcer also have bacteria called *Helicobacter pylori* in their stomach. APO-Lansoprazole ODT can be taken in conjunction with certain antibiotics to help eradicate *Helicobacter pylori* and let your peptic ulcer heal.

However, it is possible that the antibiotics may not always get rid of *Helicobacter pylori*.

How it works

APO-Lansoprazole ODT contains lansoprazole, which is a type of medicine called a proton pump inhibitor (PPI).

It works by decreasing the amount of acid the stomach makes, to give relief from the symptoms of excessive acid and allow healing to take place. This does not stop food being digested in the normal way.

Ask your doctor if you have any questions about why APO-Lansoprazole ODT has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

Before you take this medicine

When you must not take it

Do not take APO-Lansoprazole ODT if you have an allergy to:

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

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 take APO-Lansoprazole ODT if you have severe liver disease.

Do not take APO-Lansoprazole ODT if you are already taking the medicine atazanavir. Atazanavir is used to treat HIV infection. If it is taken at the same time as APO-Lansoprazole ODT, it won't be absorbed properly and will be less effective in treating HIV infection.

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 have or have had any of the following medical conditions:

- Liver or kidney problems
- A tumour in the stomach region
- Inflammation of the bowel
- Low levels of vitamin B12 or magnesium in your blood
- Osteoporosis or an increased risk of fractures
- An increased risk of infection, including pneumonia and gastrointestinal infections

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

Your doctor can discuss with you the possible risks and benefits of taking APO-Lansoprazole ODT during pregnancy.

Tell your doctor if you are breastfeeding.

It is not known if APO-Lansoprazole ODT passes into breast milk. The use of this medicine during breastfeeding should be avoided.

Tell your doctor if you 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 him or her before you start taking this medicine.

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 this one may interfere with each other. These include:

- Theophylline used to treat asthma
- Oral contraceptives
- Warfarin used to prevent blood clots
- Carbamazepine and phenytoin used to treat seizures
- Ketoconazole used to treat fungal infections
- Digoxin used to treat heart complaints
- Fluvoxamine used to treat mood disorders
- Iron preparations
- Ampicillin esters used in some antibiotics
- Tacrolimus or mycophenolate mofetil used in transplant patients to reduce organ rejection
- Atazanavir, Nelfinavir or other medicines used to treat HIV infection
- Methotrexate used to treat some cancers
- Sucralfate (used to treat gastric ulcers) and antacids (used to treat heartburn and indigestion).

APO-Lansoprazole ODT should be taken at least one hour before taking sucralfate or an antacid.

These medicines may be affected by APO-Lansoprazole ODT 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.

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

When to take it

Take APO-Lansoprazole ODT in the morning before food.

APO-Lansoprazole ODT works best when taken on an empty stomach.

How much to take

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

Adults

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

Children (6 years or older)

For children between 6 to 11 years, the recommended dose depends on the weight of the child.

For children weighing 30 kg or less, the usual dose is 15 mg daily.

For children weighing over 30 kg, the usual dose is one 30 mg tablet daily.

For children between 12 to 17 years, the dose may vary from 15 mg to 30 mg a day depending on the condition.

How to take it

Swallow the tablet whole with a glass of water, or gently suck the tablet, then swallow the granules with your saliva.

If the tablet is chewed or crushed, it will not work properly.

How long to take it

Keep taking APO-Lansoprazole ODT as directed, unless your doctor gives you other instructions.

In most patients, APO-Lansoprazole ODT relieves symptoms rapidly and healing is usually complete within 4 weeks. In some patients a further 4 weeks of treatment may be needed for complete healing.

Your doctor may want you to keep taking APO-Lansoprazole ODT on a long-term basis to prevent the condition from coming back.

APO-Lansoprazole ODT is recommended only for short-term use (8 to 12 weeks) in children.

For children aged 6 to 11 years, do not exceed 12 weeks of treatment with APO-Lansoprazole ODT.

For children aged 12 to 17 years, do not exceed 8 weeks of treatment with APO-Lansoprazole ODT.

Tell your doctor if your symptoms return.

You may need further treatment.

If you forget to take it

If it is almost time to take your next dose, skip the dose you missed and take your next dose when you are meant to.

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 the dose that you missed.

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.

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 of this medicine. Do this even if there are no signs of discomfort or poisoning.

While you are using this medicine

Things you must do

Take APO-Lansoprazole ODT exactly as your doctor has prescribed.

Tell your doctor immediately if you become pregnant while you are taking APO-Lansoprazole ODT.

If you are about to start any new medicine, remind your doctor and pharmacist that you are taking APO-Lansoprazole ODT.

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.

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.

Things you must not do

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

Do not give APO-Lansoprazole ODT to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or change 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

Be careful driving or operating machinery until you know how APO-Lansoprazole ODT affects you.

APO-Lansoprazole ODT generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, APO-Lansoprazole ODT may cause dizziness in some people. Make sure you know how you react to APO-Lansoprazole ODT before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy. If you drink alcohol, dizziness may be worse.

Children should be careful when riding bicycles or climbing trees.

Things that may help your condition

Some self-help measures suggested below may help your condition. Your doctor or pharmacist can give you more information about these measures.

- **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 that contain caffeine, such as coffee, tea, cocoa and cola drinks, because they contain ingredients that may irritate the 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 APO-Lansoprazole ODT.

This medicine helps most people with their condition, 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.

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.

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

Stomach or bowel problems such as:

- Vomiting or nausea
- Diarrhoea or constipation
- Stomach pain
- Indigestion
- Flatulence or wind.

If you suffer from severe persistent diarrhoea and/or vomiting when taking APO-Lansoprazole ODT, tell your doctor.

As natural acid in the stomach helps to kill bacteria, the lowering of acid by acid-reducing medicines such as APO-Lansoprazole ODT may cause some people to get certain stomach infections.

Difficulty thinking or working because of:

- Headache
- Dizziness
- Tiredness
- Joint or muscle aches or pains
- Generally feeling unwell
- Feeling confused, depressed or having hallucinations.

Changes to your appearance such as:

- Skin rashes
- Hives or itchy skin
- Hair thinning
- 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
- Frequent and painful passing of urine indicating a urinary tract infection
- Dry or sore mouth or throat.

Changes in your sight, hearing, taste or touch such as:

- Tingling or numbness of hands and feet
- Blurred vision
- Taste disturbances side effects, as per PI
- Increased sensitivity to sunlight.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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
- Yellowing of the skin or eyes, especially if accompanied by fever, fatigue, loss of appetite, dark coloured urine or light coloured bowel movements
- Watery and severe diarrhoea
- Pain in the kidney region
- Swelling of the face, lips, tongue or throat, which may cause difficulty breathing
- Swelling of hands, ankles or feet

- Bruising or bleeding more easily than normal, 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
- Cramping of the muscles in your hands or feet
- Irregular heartbeat
- Fits or seizures.

The above list includes serious to very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

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 APO-Lansoprazole ODT
- 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.

Storage and Presentation

Storage

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

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

Keep your 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.

Product description

What it looks like

APO-Lansoprazole ODT 15 mg tablets:

White to yellowish white uncoated tablets, speckled with orange to dark brown pellets debossed with "15" on one side of the tablet and plain on the other side.

APO-Lansoprazole ODT 15 mg is available in a blister pack of 7 or 28 tablets.

APO-Lansoprazole ODT 30 mg tablets:

White to yellowish white uncoated tablets speckled with orange to dark brown pellets debossed with "30" on one side of the tablet and plain on the other side.

APO-Lansoprazole ODT 30 mg is available in a blister pack of 7 or 28 tablets

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains either 15 mg or 30 mg of lansoprazole as the active ingredient.

It also contains the following inactive ingredients:

- Microcrystalline cellulose
- Magnesium carbonate hydrate
- Hypromellose
- Hypromellose
- Purified-talc
- Titanium dioxide
- Mannitol
- Methacrylic acid - ethyl acrylate copolymer dispersion (1:1) 30 per cent
- Polyacrylate dispersion 30per cent
- Glyceryl monostearate
- Macrogol 6000
- Polysorbate 80
- Citric acid
- Triethyl citrate
- Iron oxide yellow
- Iron oxide red
- F-melt type C
- Crospovidone
- Aspartame
- Strawberry flavour
- Magnesium stearate

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

15 mg tablet: AUST R 216788

30 mg tablet: AUST R 216794

Sponsor

Lupin Australia Pty Ltd
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Australia.

Distributor

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This leaflet was prepared in December 2022