

## APO-Lansoprazole ODT

Contains the active ingredient lansoprazole

### Consumer Medicine Information

#### 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 benefits and risks. Your doctor has weighed the risks of you taking APO-Lansoprazole ODT against the benefits this medicine is expected to have.

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 APO-Lansoprazole ODT 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 APO-Lansoprazole ODT 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 prescribe this medicine for another reason.

There is no evidence that APO-Lansoprazole ODT is habit-forming.

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

#### Before you take APO-Lansoprazole ODT

##### When you must not take it

- **Do not take APO-Lansoprazole ODT if you have an allergy to:**
  - Lansoprazole
  - Any medicines containing a proton-pump inhibitor
  - Any of the ingredients listed at the end of this leaflet.Some of the symptoms of an allergic reaction include rash, itching, or hives on the skin; shortness of breath, wheezing or difficulty breathing; and swelling of the face, lips, tongue or other parts of the body.

- **Do not take APO-Lansoprazole ODT if you have severe liver disease.**
- **Do not take APO-Lansoprazole ODT after the use by (expiry) date printed on the pack or if the packaging is torn or shows signs of tampering.**
- **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.

**If you are not sure whether you should take this medicine, talk to your doctor.**

##### Before you start to take it

###### You must tell your doctor if:

1. You have any allergies to any other medicines, foods, dyes or preservatives.
2. You are pregnant or breastfeeding or intend to become pregnant or breastfeed. Your doctor will discuss the possible risks and benefits of using APO-Lansoprazole ODT during pregnancy. It is not known if your baby can take in APO-Lansoprazole ODT from breast milk if you are breastfeeding. The use of APO-Lansoprazole ODT during breastfeeding should be avoided.
3. You have any other medical conditions, including:
  - Liver or kidney problems.
  - A tumour in the stomach region.

**If you have not told your doctor about any of the above, tell them before you take APO-Lansoprazole ODT.**

##### Taking other medicines

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

Some medicines may interfere with APO-Lansoprazole ODT. These medicines and their typical uses 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
- 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.**

- Iron preparations
- Ampicillin esters used in some antibiotics
- Tacrolimus used in transplant patients to reduce organ rejection
- Atazanavir used to treat HIV infection.

These medicines may be affected by APO-Lansoprazole ODT, or 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 take APO-Lansoprazole ODT

**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 what the condition is and how long you need treatment.

##### Children (6 years or older):

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.

##### 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. However, you may find that the pain and discomfort caused by an ulcer or heartburn will go away well before you finish taking all your medicine.

Although APO-Lansoprazole ODT heals ulcers very successfully, the ulcer may come back at a later date. Your doctor may want you to keep taking APO-Lansoprazole ODT on a long-term basis to prevent the condition from coming back. However, APO-Lansoprazole ODT is recommended only 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*

If it is almost time for the next dose, skip the missed dose and take the next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to your normal routine.

**Do not take a double dose to make up for the dose you missed.**

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

*If you take too much (overdose)*

**Immediately telephone your doctor or Poisons Information Centre (Tel 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much APO-Lansoprazole ODT.**

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

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While you are taking APO-Lansoprazole ODT

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*Things you must do*

- Take APO-Lansoprazole ODT exactly as your doctor has prescribed.
- Tell your doctor if you become pregnant while you are taking APO-Lansoprazole ODT.
- If you are about to start any new medicine, remind your doctor, dentist and pharmacist that you are taking APO-Lansoprazole ODT.
- Tell your doctor if you are about to have any blood tests.
- Tell your doctor if you are going to have surgery or an anaesthetic or are going into hospital.

*Things you must not do*

- **Do not give your medicine to anyone else, even if they have the same condition as you.**
- **Do not take APO-Lansoprazole ODT to treat any other complaints unless your doctor tells you to.**
- **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.

*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 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.

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Possible side effects

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**Tell your doctor as soon as possible if you do not feel well while taking APO-Lansoprazole ODT.**

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.

Ask your doctor or pharmacist any questions you may have.

Tell your doctor if you notice any of the following

**Tell your doctor if you notice any of the following:**

- **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
  - Increased sensitivity to sunlight
  - 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.

**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
- 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

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 making you feel unwell when taking, or soon after finishing taking, APO-Lansoprazole ODT.

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.**

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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## Storage and disposal

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### Storage

**Keep your tablets in their 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 it in a cool dry place where the temperature stays below 25°C. Do not store it or any other medicines in a bathroom or near a sink. Do not leave it in the car or on windowsills.**

Heat and dampness can destroy some medicines.

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

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

**Keep this medicine 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, your pharmacist can dispose of the remaining medicine safely.

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## Product description

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### What APO-Lansoprazole ODT 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:

- Cellulose-microcrystalline
- Magnesium carbonate-light
- Low-substituted hydroxypropyl cellulose
- Hydroxypropyl cellulose
- Hypromellose
- Talc-purified
- Titanium dioxide
- Mannitol
- Methacrylic acid - ethyl acrylate copolymer dispersion (1:1) 30 per cent
- Polyacrylate dispersion 30 per cent
- Glyceryl monostearate
- Macrogol 6000
- Polysorbate 80
- Citric acid anhydrous
- 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**  
Level 1, 1102 Toorak Road  
Camberwell VIC 3124  
Australia.

### Distributor

**Apotex Pty Ltd**  
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