

APO-Lansoprazole ODT

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking APO- Lansoprazole ODT ?

APO- Lansoprazole ODT contains the active ingredient lansoprazole, and is taken to treat peptic ulcers; reflux oesophagitis; heartburn and stomach pain associated with reflux or peptic ulcer; peptic ulcers associated with Helicobacter Pylori infection. For more information, see Section [1. Why am I taking APO- Lansoprazole ODT ?](#) in the full CMI.

2. What should I know before I take APO- Lansoprazole ODT ?

Do not take if you have ever had an allergic reaction to APO- Lansoprazole ODT , other proton pump inhibitors (PPIs) or any of the ingredients listed at the end of the CMI; have severe liver disease or are taking atazanavir.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take APO- Lansoprazole ODT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO- Lansoprazole ODT and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take APO- Lansoprazole ODT ?

Your doctor or pharmacist will tell you how much to take and for how long to take APO- Lansoprazole ODT . It needs to be taken in the morning before food, dissolved on the tongue or swallowed whole with a glass of water. More instructions can be found in Section [4. How do I take APO- Lansoprazole ODT?](#) in the full CMI.

5. What should I know while taking APO- Lansoprazole ODT ?

Things you should do	<ul style="list-style-type: none">• Tell all doctors, dentists, pharmacists and nurses who are treating you, that you are taking APO- Lansoprazole ODT .• Tell your doctor if you become pregnant while you are taking APO- Lansoprazole ODT ; or experience stomach pain, fever and diarrhoea which may contain blood/mucus, or red, itchy, blistering spots, or skin rash including peeling, with fever, weakness/fatigue or muscle pain.
Things you should not do	<ul style="list-style-type: none">• Do not breastfeed while taking APO- Lansoprazole ODT .• 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.
Alcohol & Driving/using machines	<ul style="list-style-type: none">• Be careful before you drink alcohol, or drive or use any machines or tools until you know how APO- Lansoprazole ODT affects you as APO- Lansoprazole ODT may cause dizziness in some people.
Looking after your medicine	<ul style="list-style-type: none">• Keep it in a cool dry place where the temperature stays below 25 °C.

For more information, see Section [5. What should I know while taking APO- Lansoprazole ODT?](#) in the full CMI.

6. Are there any side effects?

APO- Lansoprazole ODT is well tolerated, and side effects are generally mild and transient. Side effects may include headache, dizziness, tiredness, feeling unwell, nausea, vomiting, diarrhoea, constipation, stomach pain, indigestion, flatulence, taste disturbances, muscle/joint pain, hair thinning, increased sensitivity to sunlight. Serious side effects include severe allergic reaction (shortness of breath; wheezing/difficulty breathing; swelling of the face, lips, tongue; rash, itching or hives on the skin); signs of infection (fever, sore throat); skin rash that can include blisters and peeling; severe persistent diarrhoea and increased risk of bone fracture. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

APO- Lansoprazole ODT

Active ingredient(s): *lansoprazole*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking APO- Lansoprazole ODT . **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking APO- Lansoprazole ODT .**

Where to find information in this leaflet:

[Why am I taking APO- Lansoprazole ODT ?](#)

- [1. What should I know before I take APO- Lansoprazole ODT ?](#)
- [2. What if I am taking other medicines?](#)
- [3. How do I take APO- Lansoprazole ODT ?](#)
- [4. What should I know while taking APO- Lansoprazole ODT ?](#)
- [5. Are there any side effects?](#)
- [6. Product details](#)

1. Why am I taking APO- Lansoprazole ODT ?

APO- Lansoprazole ODT contains the active ingredient lansoprazole.

APO- Lansoprazole ODT is a type of medicine called a proton pump inhibitor (PPI). It works by reducing 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.

APO- Lansoprazole ODT is taken for:

Peptic Ulcers

APO- Lansoprazole ODT is used to treat peptic ulcers (also called gastric or duodenal ulcers) in adults.

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 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/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 a 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*.

2. What should I know before I take APO- Lansoprazole ODT ?

Warnings

Do not take APO- Lansoprazole ODT if:

- you are allergic to lansoprazole, other proton pump inhibitors (PPIs) or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take this medicine.
- you have severe liver disease
- you are already taking atazanavir, a medicine used to treat HIV infection. If atazanavir is taken at the same time as APO- Lansoprazole ODT , atazanavir will not be absorbed properly and will be less effective in treating HIV infection

Check with your doctor if you:

- had or have any other medical conditions including:
 - o kidney or liver problems
 - o inflammation of the bowel
 - o a tumour in the stomach area
 - o osteoporosis
 - o low magnesium levels
 - o glucose-galactose malabsorption
 - o a rash or skin reaction after treatment with a proton pump inhibitor medicine like APO- Lansoprazole ODT that reduces stomach acid.
- have problems with digestion, or have an intolerance to:
 - o fructose, glucose, galactose, sucrose or maltose
 - o lactose
 - o aspartame.

During treatment, you may be at risk of developing certain side effects, including fractures if treatment is long-term. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Your doctor will discuss the possible risks and benefits of taking APO- Lansoprazole ODT during pregnancy. Talk to your doctor if you are breastfeeding or intend to breastfeed. Taking APO- Lansoprazole ODT during breastfeeding should be avoided as it is not known if this medicine passes into your breast milk.

3. What if I am taking other medicines?

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

Some medicines may interfere with APO- Lansoprazole ODT and affect how it works.

- theophylline, used to treat asthma.
- carbamazepine and phenytoin, used to treat seizures (fits).
- warfarin, used to prevent blood clots.
- tacrolimus or mycophenolate, immune suppressants used in transplant patients to reduce organ rejection.
- fluvoxamine, used to treat depression and other mental health conditions.
- oral contraceptives (birth control pills).
- ampicillin esters, used in some antibiotics.
- ketoconazole, used to treat fungal infections.
- iron preparations.
- digoxin, used to treat heart conditions.
- methotrexate, used in rheumatoid arthritis, psoriasis and certain cancers.
- atazanavir, nelfinavir and other HIV medicines.
- sucralfate (used to treat stomach ulcers) and antacids (used to treat heartburn and indigestion).

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APO- Lansoprazole ODT .

4. How do I take APO- Lansoprazole ODT ?

How much to take

Your doctor or pharmacist will tell you how much to take and for how long to take APO- Lansoprazole ODT as it depends on the condition you are taking it for.

Adults

The usual dose for adults is 30 mg once daily. The dose may vary from 15 mg daily to 30 mg twice daily depending on the condition being treated.

Children

6 to 11 years old

The recommended dose for this age group depends on the weight of the child.

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

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

12 to 17 years old

The usual dose may vary from 15 mg to 30 mg once daily depending on the condition being treated.

When to take APO- Lansoprazole ODT

APO- Lansoprazole ODT should be taken in the morning before food.

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

How to take APO- Lansoprazole ODT

There are two ways you can take:

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

Do not chew or crush the tablet as this affects how well APO- Lansoprazole ODT works.

How long to take APO- Lansoprazole ODT

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.

In some cases, your doctor may decide that long term treatment is needed.

Tell your doctor if any of your symptoms return after stopping long term treatment.

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 APO- Lansoprazole ODT

APO- Lansoprazole ODT should be taken regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to your normal routine.

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.

If you take too much APO- Lansoprazole ODT

If you think that you have taken too much APO- Lansoprazole ODT , you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking APO- Lansoprazole ODT ?

Things you should do

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

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

Tell all doctors, dentists, pharmacists and nurses who are treating 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.

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

Discuss the need for any additional supplements (e.g. vitamin D, magnesium, calcium, vitamin B12), with your doctor, especially if taking APO- Lansoprazole ODT long-term.

Immediately alert your doctor if you experience:

- stomach pain and fever with diarrhoea which may contain blood or mucus
- red, itchy, blistering spots on skin, or a rash that may include peeling, and may be accompanied by fever, weakness, fatigue or muscle pain.

Things you should not do

- Do not breastfeed while taking APO- Lansoprazole ODT.
- 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.

Driving or taking machines

Be careful before you drive or take any machines or tools 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.

Drinking alcohol

As you may experience dizziness when taking APO- Lansoprazole ODT , drinking alcohol may make the dizziness 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 mealtimes. 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.

Looking after your medicine

- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
<ul style="list-style-type: none"> headache dizziness, vertigo tiredness and generally feeling unwell nausea, vomiting diarrhoea, constipation, stomach pain indigestion, flatulence joint/muscle aches or pain feeling confused, depressed or hallucinating skin rash, hives or itchy skin hair thinning breast enlargement and impotence in men coughs, colds, sore throats or sinuses indicating an upper respiratory tract infection frequent and painful passing of urine/wee indicating a urinary tract infection dry or sore mouth or throat tingling or numbness of hands and feet blurred vision increased sensitivity to sunlight taste disturbances swelling of the hands, ankles or feet 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Allergy and immune related</p> <ul style="list-style-type: none"> 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 (severe allergic reaction) <p>Liver related</p> <ul style="list-style-type: none"> yellowing of the skin or eyes, especially if accompanied by fever, fatigue, loss of appetite, dark coloured urine/wee or light-coloured bowel movements <p>Bowel related</p> <ul style="list-style-type: none"> diarrhoea, usually with blood and mucus, stomach pain, fever <p>Kidney related</p>	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> pain in the lower back or side, painful urination, fever, fatigue, swelling of hands, ankles or feet <p>Blood related</p> <ul style="list-style-type: none"> frequent infections such as fever, severe chills, sore throat or mouth ulcers bruising or bleeding more easily than normal, bleeding under the skin or red or purple flat pinhead spots under the skin muscle cramp or weakness of the muscles in your hands or feet, abnormal heart rhythms, difficulty breathing, tingling and numbness, fits or seizures <p>Skin related</p> <ul style="list-style-type: none"> 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 skin rash that can include blisters, peeling and may be accompanied by fever, weakness and fatigue <p>Bone related</p> <ul style="list-style-type: none"> pain, swelling, bruising or discolouration, unusual shape of the limb, weakness and difficulty moving the limb indicating a fracture 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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.

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.

Reporting side effects

After you have received medical advice for any side-effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What APO- Lansoprazole ODT contains

Active ingredient (main ingredient)	lansoprazole
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Microcrystalline cellulose• magnesium carbonate hydrate• hyprollose• purified-talc• mannitol• methacrylic acid-ethyl acrylate copolymer dispersion (1:1)• polyacrylate dispersion (30%)• macrogol 6000• citric acid• glyceryl monostearate• polysorbate 80• triethyl citrate• iron oxide yellow• iron oxide red• F-melt type C (PI 106551)• crospovidone• magnesium stearate• strawberry flavor (PI 105990)• aspartame.
Potential allergens	<ul style="list-style-type: none">• lactose monohydrate• aspartame

Do not take this medicine if you are allergic to any of these ingredients.

APO- Lansoprazole ODT does not contain gluten, tartrazine or any other azo dyes.

What APO- Lansoprazole ODT looks like

APO- Lansoprazole ODT 15 mg tablets are white to yellowish-white, uncoated tablets, speckled with orange to dark brown pellets debossed with "I5" on one side of the tablet and plain on the other side. (AUST R 216788)

APO- Lansoprazole ODT 30 mg tablets are 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. (AUST R 216794)

Sponsor

Lupin Australia Pty Ltd
Suite 2, Level 2, 19-23 Prospect Street
Box Hill VIC 3128
Australia.

Who distributes APO- Lansoprazole ODT

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121
www.arrotex.com.au

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