

APO-LANSOPRAZOLE

Consumer Medicine Information (CMI) summary

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

1. Why am I taking APO-LANSOPRAZOLE?

APO-LANSOPRAZOLE 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?](#) in the full CMI.

2. What should I know before I take APO-LANSOPRAZOLE?

Do not take if you have ever had an allergic reaction to APO-LANSOPRAZOLE, 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.

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

3. What if I am taking other medicines?

Some medicines may interfere with APO-LANSOPRAZOLE 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?

Your doctor or pharmacist will tell you how much to take and for how long to take APO-LANSOPRAZOLE. It needs to be taken in the morning before food. The capsule should be swallowed whole with plenty of water. Do not crush or chew.

More instructions can be found in Section [4. How do I take APO-LANSOPRAZOLE?](#) in the full CMI.

5. What should I know while taking APO-LANSOPRAZOLE?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist, nurses or pharmacist who are treating you, that you are taking APO-LANSOPRAZOLE.Tell your doctor if you become pregnant while you are taking APO-LANSOPRAZOLE; 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.Do not give your medicine to anyone else, even if they have the same condition as you.Do not take APO-LANSOPRAZOLE to treat any other complaints unless your doctor tells you to.
Alcohol & Driving or 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 affects you as APO-LANSOPRAZOLE 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?](#) in the full CMI.

6. Are there any side effects?

APO-LANSOPRAZOLE 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

Active ingredient(s): *lansoprazole*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking APO-LANSOPRAZOLE?

APO-LANSOPRAZOLE contains the active ingredient lansoprazole.

APO-LANSOPRAZOLE 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 is taken for:

In Adults it used to treat,

- **Reflux Oesophagitis**

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.

- **Peptic ulcers (also called gastric or duodenal ulcers).**

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

- **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 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*.

- **Heartburn and stomach pain associated with reflux or peptic ulcer.**

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

In children aged 6-17 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.

There is no evidence that this medicine is addictive.

2. What should I know before I take APO-LANSOPRAZOLE?

Warnings

Do not take APO-LANSOPRAZOLE 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 use this medicine.
- you have severe liver disease
- you are taking atazanavir, a medicine used to treat HIV infection. If atazanavir is taken at the same time as APO-LANSOPRAZOLE, 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:
 - kidney or liver problems
 - inflammation of the bowel
 - a tumour in the stomach area
 - osteoporosis
 - low magnesium levels
 - a rash or skin reaction after treatment with a proton pump inhibitor medicine like APO-LANSOPRAZOLE that reduces stomach acid.
 - fructose intolerance, glucose galactose malabsorption or sucrose-isomaltase insufficiency.

During treatment, you may be at risk of developing certain side effects. 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 during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Taking APO-LANSOPRAZOLE 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 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).

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

These medicines may be affected by lansoprazole or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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.

4. How do I take APO-LANSOPRAZOLE?

How much to take

Your doctor or pharmacist will tell you how much to take and for how long to take APO-LANSOPRAZOLE 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 years or older)

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

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 daily.

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

When to take APO-LANSOPRAZOLE

APO-LANSOPRAZOLE should be taken in the morning before food.

APO-LANSOPRAZOLE works best when taken on an empty stomach.

How to take APO-LANSOPRAZOLE

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 swallow 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.

How long to take APO-LANSOPRAZOLE

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

In most patients, APO-LANSOPRAZOLE 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 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.

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

Tell your doctor if your symptoms return.

You may need further treatment.

If you forget to take APO-LANSOPRAZOLE

APO-LANSOPRAZOLE should be used 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 use too much APO-LANSOPRAZOLE

If you think that you have used too much APO-LANSOPRAZOLE, 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?

Things you should do

Take APO-LANSOPRAZOLE 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.

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.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. APO-LANSOPRAZOLE may interfere with the results of some tests.

Keep all your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure lansoprazole is working and to prevent unwanted side effects.

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

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

Call your doctor straight away 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.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not take APO-LANSOPRAZOLE 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 using machines

Be careful before you drive or use any machines or tools until you know how APO-LANSOPRAZOLE affects you.

APO-LANSOPRAZOLE generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, APO-LANSOPRAZOLE may cause dizziness in some people. Make sure you know how you react to APO-LANSOPRAZOLE 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, 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 capsules in their blister pack until it is time to take them.
- If you take the capsules 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 window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

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

Do not use 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.

Less serious side effects

Less serious 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 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> • impotence in men • coughs, colds, sore throat 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 	
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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> <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 	<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>

<p>the skin that are exposed to the sun and is accompanied by joint pain</p> <ul style="list-style-type: none"> • skin rash that can include blisters, peeling and may be accompanied by fever, weakness and fatigue <p>Bone related</p> <p>pain, swelling, bruising or discolouration, unusual shape of the limb, weakness and difficulty moving the limb indicating a fracture</p>	
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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 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.
- 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 contains

Active ingredient (main ingredient)	Each APO-LANSOPRAZOLE Enteric Capsules contains 15 mg or 30 mg of lansoprazole as active ingredient.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • sucrose • maize starch • purified talc • hypromellose • titanium dioxide

	<ul style="list-style-type: none"> • methacrylic acid-ethyl acrylate copolymer (1:1) • macrogol 300 • colloidal anhydrous silica • gelatin • Opacode S-1-277002 black <p>The 15 mg enteric capsule also contains the below colourants:</p> <ul style="list-style-type: none"> • iron oxide yellow CI77492 • quinoline yellow CI47005 <p>The 30 mg enteric capsule also contains the below colourants:</p> <ul style="list-style-type: none"> • indigo carmine CI73015 • carmoisine CI14720
Potential allergens	Contains sugars as sucrose. Contains sulfites.

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

This medicine does not contain gluten and lactose.

What APO-LANSOPRAZOLE looks like

APO-LANSOPRAZOLE 15 mg capsule:

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. AUST R 159350. AUST R 159346.

APO-LANSOPRAZOLE 30 mg capsule:

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. AUST R 159345. AUST R 159348.

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

Who distributes APO-LANSOPRAZOLE

Arrotex Pharmaceuticals Pty Ltd

15 – 17 Chapel Street

Cremorne VIC 3121

www.arrotex.com.au

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