

# **APO-Lansoprazole Capsules**

Contains the active ingredient, Lansoprazole

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## **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.  
Ask your doctor or pharmacist if you do not understand anything or are worried about 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.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits it is expected to have for you.

**Keep this leaflet with the medicine.**

You may need to read it again.

## **What lansoprazole is used for**

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

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.

### **Reflux Oesophagitis (inflammation of oesophagus):**

Lansoprazole is used to treat the symptoms of reflux oesophagitis or reflux disease in adults and in children from 1 to 17 years of age. This can be caused by backflow (reflux) of food and acid from the stomach into the food pipe, also known as the oesophagus. Reflux can cause a burning sensation in the chest rising up to the throat, also known as heart burn.

### **Peptic Ulcers (Ulcers of stomach or duodenum):**

Lansoprazole 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. These can be caused in part by too much acid being made in the stomach.

Lansoprazole is also used for the treatment:

- to stop duodenal ulcers from coming back
- of infections caused by the bacteria *Helicobacter pylori* when given in combination with antibiotic therapy
- of heartburn and acid regurgitation.

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

## **Before you take lansoprazole**

### **When you must not take it**

**Do not take this medicine if you are allergic to lansoprazole, any medicines containing a proton-pump inhibitor or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include skin rash, itchiness or hives, shortness of breath, wheezing or difficulty breathing, swelling of the tongue, lips, face or other parts of the body.

**Do not take this medicine if you have severe problems with your liver.**

**Do not take this medicine after the expiry date (EXP) printed on the pack.**

If you take it after the expiry date has passed, it may not work as well.

**Do not take this medicine if the capsules do not look quite right.**

**Do not take this medicine 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 or pharmacist.**

## **Before you start to use it**

**Tell your doctor if:**

**1. Have any allergies to:**

- any other medicines
- any other substances, such as foods, dyes or preservative.

**2. You have or have had any medical conditions, especially the following:**

- problems with your kidney(s) or liver
- an abnormal growth (tumour) in stomach.

**3. You plan to become pregnant or breastfeed.**

Your doctor will discuss the possible risks and benefits of taking this medicine. Lactating women should not breast-feed while taking lansoprazole.

**If you have not told your doctor about any of the above, tell them before you start taking this medicine.**

## Taking other medicines

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

Some medicines and lansoprazole may interfere with each other. These include:

- Theophylline, used to treat asthma
- Carbamazepine and phenytoin used to treat fits (seizures)
- Warfarin, used to prevent blood clot
- Oral contraceptive
- Sucralfate (use to treat stomach ulcers) and antacids (used to treat heartburn). APO-Lansoprazole should be taken at least an hour prior sucralfate or antacid administration.
- Ampicillin esters and clarithromycin antibiotic
- Ketoconazole used to treat fungal infection
- Iron salt preparation
- Digoxin for cardiac complication

These medicines may be affected by lansoprazole 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 and pharmacist can tell you if you are taking any of these medicines. They may also have more information on

medicines to be careful with or avoid while taking lansoprazole.

Other interactions not listed above may also occur.

## **How to take this medicine**

Follow all directions given to you by your doctor or pharmacist carefully.

This may differ from the information contained in this leaflet.

If you do not understand any written instructions, ask your doctor or pharmacist for help.

## **How much to take**

**Take one lansoprazole capsule each day, unless your doctor has told you otherwise.**

### **Adults**

The dose to be taken depends on what your condition is and how long you require treatment. It may vary from 15 mg to 30 mg per day.

### **Children and Adolescents (1-17 years old)**

The recommended dose depends on the weight of the child or adolescent.

For those weighing 30 kg or less, the usual dose is one APO-Lansoprazole 15 mg capsule daily.

For those weighing over 30 kg, the usual dose is one APO-Lansoprazole 30 mg capsule daily.

## **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, you can open a capsule and administered as follows:

- Sprinkle intact granules on one tablespoon of apple sauce, strained pears, cottage cheese or yoghurt and swallow immediately.
- The capsules may also be emptied 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 it in the morning before food.

## **How long to take it**

Continue taking the capsules for as long as your doctor tells you. Do not stop taking it unless your doctor tells you to, even if you feel better.

In most patients, lansoprazole relieves symptoms rapidly and healing is usually complete within 4 weeks, although the pain and discomfort caused by the ulcer or reflux may go away well before all the prescribed capsules have been finished.

Although lansoprazole heals ulcers very successfully, it may not prevent them from coming back at a later date. Your doctor may want you to keep taking this medicine long-term to prevent the condition from recurring. However, lansoprazole is only recommended 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 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 it as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

If you have missed more than one dose, or are not sure what to do, check with 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 (Tel: 13 11 26 for Australia) for advice, or go to Accident & Emergency Department at your nearest hospital, if you think that you or anyone else may have taken too much lansoprazole.**

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

You may need urgent medical attention.

Keep these numbers handy in case of an emergency.

## **While you are taking this medicine**

### **Things you must do**

Take this medicine exactly as your doctor has prescribed.

Tell all doctors, dentist and pharmacists who are treating you that you are taking lansoprazole.

Tell your doctor immediately if you become pregnant.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

Go to your doctor regularly for a check-up.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

## **Things you must not do**

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

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

Do not stop taking this medicine, or change the dosage, without checking with your doctor.

## **Things to be careful of**

Be careful driving or operating machinery until you know how lansoprazole affects you.

Lansoprazole may cause dizziness or light-headedness in some people.

If you drink alcohol, dizziness or light-headedness 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 which contain caffeine, such as coffee, tea, cocoa and cola drinks, because they contain ingredients that may irritate your stomach.

- **Eating habits**

- eat smaller, more frequent meals. Eat slowly and chew your food carefully. Try not to rush at meal times.

- **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 of lansoprazole**

All medicines may have some side effects. Sometimes they are serious, but most of the time, they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Tell your doctor or pharmacist as soon as possible if you do not feel well while taking lansoprazole.

Ask your doctor or pharmacist to answer any questions you may have.

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

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

### **Stomach or bowel problems such as:**

- diarrhoea, constipation
- indigestion nausea (feeling sick), vomiting (being sick)
- 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)
- light-headedness, feeling like you may faint
- generally feeling unwell
- joint or muscle aches or pain
- feeling depressed or confused
- having hallucinations

**Changes to appearance such as:**

- thinning hair
- 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

- dry or sore mouth or throat
- frequent and painful passing of urine indicating urinary tract infection

**Changes in sight, hearing, taste or touch including:**

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

These are more common side effects of lansoprazole.

**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 problem#

- 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
- sudden signs of allergy such as rash, itching, or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing

# These side effects may occur when lansoprazole is used in combination with antibiotics for H. pylori infection.

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 that make you feel unwell.

## **After taking this medicine**

### **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.

## **Where to go for further information**

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

## **Product description**

### **What APO-Lansoprazole looks like**

**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 30 mg is available in blister packs of 28 capsules.

## **Ingredients**

Each APO-Lansoprazole Capsules contains 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 30 mg capsule contains the colourants:

- indigo carmine CI73015
- carmoisine CI14720.

The capsules are imprinted with the black ink Opacode-S-1-27794.

This medicine does not contain gluten and lactose.

## **Australian Registration Numbers**

APO- Lansoprazole 30 mg capsule: AUST R 159345

## **Sponsor**

Apotex Pty Ltd

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Australia

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