

# Zopral

contains the active ingredient lansoprazole

## CONSUMER MEDICINE INFORMATION

### What is in this leaflet

This leaflet answers some common questions about Zopral.

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 Zopral against the benefits expected for you.

**If you have any concerns about taking this medicine, talk to your doctor or pharmacist.**

**Keep this leaflet with your medicine.**

You may need to read it again.

### What Zopral is used for

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

Zopral belongs to a group of medicines called proton pump inhibitors (PPI).

It works by reducing the amount of acid made by the stomach. This helps reduce pain and allows any damage to heal.

#### Ulcers

Zopral is used to treat peptic ulcers.

Depending on the position of the peptic 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.

Zopral may be used alone, or in combination with other medicines, to treat your condition.

Zopral may also be used to help stop ulcers from coming back once they have healed.

#### Reflux Oesophagitis

Zopral is used to treat the symptoms of reflux oesophagitis or reflux disease in adults and in children from 1 to 17 years of age.

Reflux can be caused by a backflow of food and acid from the stomach into the food pipe.

**Ask your doctor if you have any questions about why Zopral has been prescribed for you.**

Your doctor may have prescribed Zopral for another reason.

Zopral is available only with a doctor's prescription.

There is no evidence that Zopral is addictive.

### Before you take Zopral

#### When you must not take it

**Do not take Zopral if you have an allergy to:**

- any medicine containing lansoprazole
- any of the ingredients listed at the end of this leaflet.
- any other similar medicines.

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 Zopral if you have severe liver disease.**

**Do not take Zopral after the expiry date printed on the pack or if the pack 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, dyes or preservatives.**

**Tell your doctor if you have or have had liver or kidney problems.**

**Tell your doctor if you have or have had a tumour in the stomach region.**

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

Your doctor can discuss with you the risks and benefits involved.

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

#### Taking other medicines

**Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from a**

## pharmacy, supermarket or health food shop.

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

- theophylline a medicine used to treat asthma
- oral contraceptives
- warfarin, a medicine used to prevent blood clots
- carbamazepine and phenytoin, medicines used to treat seizures
- ketoconazole, a medicine used to treat fungal infections
- digoxin, a medicine used to treat heart complaints
- iron preparations
- ampicillin esters used in some antibiotics.

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

### **Take Zopral at least one hour before taking sucralfate or an antacid.**

Sucralfate is a medicine used to treat gastric ulcers.

Antacids are medicines used to treat heartburn and indigestion.

Your doctor or pharmacist have more information on medicines to be careful with or to avoid while taking Zopral.

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## How to take Zopral

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### **Follow all directions given to you by your doctor and 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.**

## ***How much to take***

### **Take one Zopral capsule once a day, as advised by your doctor.**

Your doctor may increase or decrease your dose depending on your condition.

#### **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 (1 year or older)**

The recommended dose depends on the weight of the child.

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

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

## ***How to take it***

### **Swallow the capsules whole with a glass of water.**

### **Do not crush or chew the capsules.**

If the granules in the capsules are crushed or chewed they will not work properly.

### **If you have difficulty swallowing the capsules whole, empty the capsule contents onto some food or drink by following these instructions.**

The capsules may be emptied onto a small amount of either apple sauce, strained pears, cottage cheese or yoghurt and used like this:

- open the capsule
- do not crush the granules
- sprinkle the granules onto one tablespoon of apple sauce, strained pears, cottage cheese or yoghurt
- swallow immediately.

The capsules may be emptied into a small amount of either apple juice, orange juice or tomato juice and used like this:

- open the capsule

- do not crush the granules
- sprinkle the granules into a small amount of apple juice, orange juice or tomato juice.
- stir and swallow the mixture immediately
- to make sure that you get the full dose, rinse the glass two or three times with more juice and swallow it immediately each time.

### **Do not take Zopral with any other food or drink.**

## ***When to take it***

### **Take your medicine on an empty stomach in the morning. For example, 1 hour before food.**

Zopral works best when taken on an empty stomach.

### **Take your medicine at about the same time each day.**

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

## ***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 the missed dose as soon as you remember, and then go back to taking your capsules 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 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.**

## ***How long to take it for***

### **Continue taking Zopral for as long as your doctor tells you to.**

It is important to keep taking your medicine even if you feel well.

**Tell your doctor if your symptoms return.**

You may need further treatment.

### ***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 you or anyone else may have taken too much Zopral. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

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## **While you are taking Zopral**

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### ***Things you must do***

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Zopral.**

**Tell any other doctors, dentists and pharmacists who treat you that you are taking Zopral.**

**If you become pregnant while taking Zopral, tell your doctor.**

### ***Things you must not do***

**Do not use Zopral to treat any other complaints unless your doctor tells you to.**

**Do not give Zopral to anyone else, even if they have the same condition as you.**

### ***Things to be careful of***

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

This medicine may cause dizziness and tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Children should be careful when riding bicycles or climbing trees.

**If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.**

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

### ***Things that may help your condition***

**By following these simple measures, you can further help your condition.**

- limit alcohol intake
- limit caffeine intake
- stop smoking or at least cut down the number of cigarettes you smoke
- maintain a healthy weight.

**Aspirin and similar medicines used to treat, for example, arthritis, period pain or headache may irritate the stomach and may make your condition worse.**

Your doctor or pharmacist can suggest other medicines you may take.

**Consider your eating habits by:**

- eating smaller quantities of food at regular meal times
- do not skip meals.
- eat slowly and chew your food carefully
- try not to rush at meal times

**Talk to your doctor or pharmacist about these measures and ask for more information.**

### ***Side effects***

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

This medicine helps most people with heartburn and peptic ulcer symptoms, but it may have unwanted side effects in some 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 this list of possible side effects.**

You may not experience any of them.

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

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

- headache
- dizziness, especially when getting up from a lying or sitting position
- tiredness
- generally feeling unwell
- indigestion
- flatulence or wind.

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

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

- diarrhoea or constipation
- stomach pain
- joint pain or painful, swollen joints
- aching muscles, muscle tenderness or weakness, not caused by exercise
- tingling or numbness of hands and feet
- feeling confused or depressed
- blurred vision
- taste disturbances
- hair thinning
- increased sensitivity of the skin to sunlight or symptoms of sunburn, which may occur more quickly than normal

The above list includes serious side effects that may require medical attention. Serious side are rare.

**If any of the following happen, tell your doctor immediately or go to**

## Accident and Emergency at your nearest hospital:

- signs of allergy such as skin rash, itching or hives, swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or troubled breathing
- yellowing of the skin and/or eyes
- nausea, vomiting, loss of appetite, light coloured bowel motions or dark coloured urine
- watery and severe diarrhoea
- passing black or blood-stained motions
- pain in the kidney region
- swelling of hands, ankles or feet
- bruising or bleeding more easily than normal
- unusual bleeding or bruising under the skin
- red, itchy blistering spots
- purple or red-brown spots visible through the skin
- red or purple flat pinhead spots under the skin
- signs of infection such as fever, severe chills, sore throat or mouth ulcers.
- frequent and painful passing of urine indicating a urinary tract infection
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- hallucinations.

The above list includes 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.

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## After taking Zopral

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### **Storage**

**Keep your capsules in the pack, until it is time to take them.**

If you take the capsules out of the pack, they may not keep well.

**Keep your capsules in a cool, dry place where the temperature stays below 25°C.**

**Do not keep Zopral or any other medicine in the bathroom or near a sink. Do not leave it 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 Zopral, or your capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.**

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## Product description

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### **What it looks like**

#### **Zopral 15 mg**

White to off-white capsules imprinted with 'MYLAN' over 'LN 15' on both cap and body in black ink.

Each blister pack contains 30 capsules.

#### **Zopral 30 mg**

White to off-white capsules imprinted with 'MYLAN' over 'LN 30' on both cap and body in black ink.

Each blister pack contains 28 capsules.

## **Ingredients**

The active ingredient in Zopral is lansoprazole.

Each Zopral 15 mg and 30 mg enteric capsule contains 15 mg or 30 mg of lansoprazole respectively.

The capsules also contain the following inactive ingredients:

- sugar spheres (ARTG No. 1014)
- magnesium carbonate
- sucrose
- starch - maize
- low-substituted hydroxypropylcellulose
- hydroxypropylcellulose-LF
- methacrylic acid copolymer : ethyl acrylate dispersion 30% (1:1)
- talc - purified
- macrogol 6000
- titanium dioxide
- polysorbate 80
- silica - colloidal anhydrous
- empty hard gelatin capsule Shell Size "2" (ARTG No. 105986) [15 mg capsule only]
- empty hard gelatin capsule Shell Size "0" (ARTG No. 105985) [30 mg capsule only]
- Tek Print Ink SW-9009 (ARTG No. 2343).

### **Supplier**

Zopral is supplied in Australia by:

Alphapharm Pty Limited  
(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

Medical Information

Phone: 1800 028 365

Australian registration numbers:

- Zopral lansoprazole 15 mg enteric capsules blister pack - Aust R 166764

- Zopral lansoprazole 30 mg enteric capsules blister pack - Aust R 166765

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