

ZOPRAL® & ZOPRAL® 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 ZOPRAL & ZOPRAL ODT?

ZOPRAL & ZOPRAL ODT contains the active ingredient lansoprazole. ZOPRAL & ZOPRAL ODT are used to treat peptic ulcers, reflux oesophagitis, heartburn and stomach pain associated with reflux, or peptic ulcer and peptic ulcers associated with helicobacter pylori infection. For more information, see Section [1. Why am I taking ZOPRAL & ZOPRAL ODT?](#) in the full CMI.

2. What should I know before I take ZOPRAL & ZOPRAL ODT?

Do not take if you have ever had an allergic reaction to lansoprazole or any of the ingredients listed at the end of the CMI.

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 ZOPRAL & ZOPRAL ODT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ZOPRAL & ZOPRAL 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 ZOPRAL & ZOPRAL ODT?

- Take ZOPRAL & ZOPRAL ODT in the morning before food.
- Swallow whole with a glass of water. Do not crush or chew the capsules.
- More instructions can be found in Section [4. How do I take ZOPRAL & ZOPRAL ODT?](#) in the full CMI.

5. What should I know while taking ZOPRAL & ZOPRAL ODT?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking ZOPRAL & ZOPRAL ODT. • If you become pregnant while taking this medicine, tell your doctor immediately. • Tell your doctor if any of your symptoms return after stopping treatment.
Things you should not do	• Do not stop taking this medicine or change the dosage without checking with your doctor.
Driving or taking machines	• Be careful driving or operating machinery until you know how the medicine affects you. ZOPRAL or ZOPRAL ODT may cause dizziness, blurred vision or headache.
Drinking alcohol	• Be careful when drinking alcohol while you are taking this medicine. If you drink alcohol, dizziness may be worse.
Looking after your medicine	• Keep your medicine in a cool dry place where the temperature stays below 25°C. • Store in original container.

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

6. Are there any side effects?

Less serious side effects: stomach or bowel problems, headache, dizziness, tiredness, muscle aches, confused, depressed, hallucinations, skin rashes, upper respiratory tract infection, urinary tract infection, tingling or numbness of hands and feet, blurred vision, sensitivity to sunlight, taste disturbances. **Serious side effects:** red, itchy blistering spots, joint pain, watery & severe diarrhoea, swelling which may cause difficulty breathing, yellowing of the skin or eyes, fever, fatigue, loss of appetite, dark coloured urine, light coloured bowel movements, pain in the kidney region, swelling of the hands, ankles or feet, bruising, severe blisters, bleeding, sudden or severe hives or itchy skin accompanied by fever, infections, cramping of the muscles in your hands or feet, irregular heartbeat, fits or seizures. **Tell your doctor immediately if you notice pain or indigestion occurring during treatment, vomiting blood or food, passing of black (blood-stained) bowel motions as these are likely to arise from the ulcer itself rather than the treatment. This is not a complete list of all possible side effects.**

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.

ZOPRAL® & ZOPRAL® ODT

Active ingredient: *lansoprazole*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking ZOPRAL & ZOPRAL 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 ZOPRAL & ZOPRAL ODT.**

Where to find information in this leaflet:

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

1. Why am I taking ZOPRAL & ZOPRAL ODT?

ZOPRAL & ZOPRAL ODT contains the active ingredient lansoprazole. ZOPRAL & ZOPRAL ODT 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.

ZOPRAL & ZOPRAL ODT are used for the following conditions:

Peptic Ulcers

ZOPRAL & ZOPRAL ODT are used to treat peptic ulcers in adults. Depending on the position of the ulcer, it is either 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.

ZOPRAL and ZOPRAL ODT are also used to help stop duodenal ulcers from coming back.

Reflux Oesophagitis

ZOPRAL and ZOPRAL ODT are 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

ZOPRAL and ZOPRAL ODT are 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. ZOPRAL and ZOPRAL 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*.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

There is no evidence that ZOPRAL and ZOPRAL ODT are habit-forming.

2. What should I know before I take ZOPRAL & ZOPRAL ODT?

Warnings

Do not take ZOPRAL & ZOPRAL ODT 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. 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

Always check the ingredients to make sure you can take this medicine.

- **you have severe liver disease**
- **you are already taking the medicine atazanavir**

Atazanavir is used to treat HIV infection. If it is taken at the same time as ZOPRAL or ZOPRAL ODT, it won't be absorbed properly and will be less effective in treating HIV infection.

Do not take this medicine after the expiry date printed on the pack or 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.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.

- have any other medical conditions:
 - liver or kidney problems
 - inflammation of the bowel
 - a tumour in the stomach region
- have problems with digestion, or have an intolerance to:
 - fructose
 - glucose
 - galactose
 - lactose
 - sucrose
- take any medicines for any other condition.

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 can discuss with you the risks and benefits of taking ZOPRAL or ZOPRAL ODT during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Taking ZOPRAL or ZOPRAL ODT during breastfeeding should be avoided as it is not known if this medicine passes into your breast milk.

If you have not told your doctor about any of the above, tell them before you start taking ZOPRAL or ZOPRAL ODT.

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 ZOPRAL & ZOPRAL ODT and affect how it works. These 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). **ZOPRAL and ZOPRAL 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 or other medicines used to treat HIV infection
- methotrexate used to treat some cancers.

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

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

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

4. How do I take ZOPRAL & ZOPRAL ODT?

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 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 your condition.
- **Children (6 years or older)**
 - 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 tablet 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 ZOPRAL & ZOPRAL ODT

- **ZOPRAL & ZOPRAL ODT should be taken in the morning before food.**

This medicine works best when taken on an empty stomach.

How to take ZOPRAL & ZOPRAL ODT

ZOPRAL (capsules)

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 as follows:

The capsules may be emptied onto a small amount of either apple sauce, strained pears, cottage cheese or

yoghurt. Alternatively, the capsules may be emptied into a small amount of apple, orange or tomato juice.

- open the capsule
- do not crush the granules
- sprinkle the granules onto one tablespoon of apple sauce, strained pears, cottage cheese or yoghurt or into a small amount of apple, orange or tomato juice
- swallow immediately. If drinking, rinse the glass two or three times with more juice and swallow immediately each time.

Do not take ZOPRAL with any other food or drink.

ZOPRAL ODT (tablets)

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 ZOPRAL or ZOPRAL ODT

- Continue taking your medicine for as long as your doctor tells you.
- In most patients, ZOPRAL or ZOPRAL 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.
- ZOPRAL and ZOPRAL ODT are recommended only for short-term use (8 to 12 weeks) in children.
- For children aged 6-11 years, do not exceed 12 weeks of treatment with ZOPRAL or ZOPRAL ODT.
- For children aged 12-17 years, do not exceed 8 weeks of treatment with ZOPRAL or ZOPRAL ODT.
- **Tell your doctor if your symptoms return. You may need further treatment.**

If you forget to take ZOPRAL & ZOPRAL ODT

ZOPRAL & ZOPRAL ODT should be taken regularly at the same time each day.

If you miss your dose at the usual time, and 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 your medicine 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 when to take your medicine, ask your pharmacist for some hints.

If you take too much ZOPRAL & ZOPRAL ODT

If you think that you or anyone else may have taken too much ZOPRAL & ZOPRAL ODT, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 ZOPRAL & ZOPRAL ODT?

Things you must do

Take ZOPRAL or ZOPRAL ODT exactly as your doctor has prescribed.

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

Call your doctor straight away if you:

- become pregnant while taking this medicine

Remind any doctor, dentist or pharmacist you visit that you are taking ZOPRAL & ZOPRAL ODT.

Things you must not do

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

- **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.

Driving or taking machines

Be careful before you drive or take any machines or tools until you know how ZOPRAL & ZOPRAL ODT affects you.

This medicine generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, ZOPRAL or ZOPRAL ODT may cause dizziness, blurred vision or headache in some people.

Make sure you know how you react to ZOPRAL or ZOPRAL ODT before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.

Drinking alcohol

Tell your doctor if you drink alcohol.

Your doctor may advise you to limit your alcohol intake.

Be careful when drinking alcohol while you are taking this medicine. If you drink alcohol, dizziness may be worse.

Looking after your medicine

- Keep your medicine in a cool dry place where the temperature stays below 25°C.
- Keep your medicine in the pack until it is time to take them. If you take the capsules or tablets out of the pack they may not keep well.

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.

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

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?

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

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.

Do not be alarmed by the following list of side effects. You may not experience any of them.

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
• Stomach or bowel problems such as: ○ diarrhoea or constipation ○ stomach pain ○ indigestion ○ vomiting or nausea ○ flatulence or wind If you suffer severe persistent diarrhoea and/or vomiting when taking ZOPRAL or ZOPRAL ODT, tell your doctor. As natural acid in the stomach helps to kill bacteria, the lowering of this stomach acid by acid-reducing medicines such as ZOPRAL and ZOPRAL ODT may cause some people to get certain stomach infections. • difficulty in thinking or working because of: ○ headache ○ dizziness ○ tiredness ○ generally feeling unwell ○ joint or muscle aches or pains ○ feeling confused, depressed or having hallucinations • experience changes to your appearance such as: ○ skin rashes ○ hives or itchy skin ○ hair thinning ○ breast enlargement and impotence in men with long term use • experience any signs of infection such as: ○ coughs, colds, sore throats or sinuses indicating an upper respiratory tract infection	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
○ frequent and painful passing of urine indicating a urinary tract infection ○ dry or sore mouth/throat ● changes in your sight, hearing, taste or touch such as: ○ tingling or numbness of hands and feet ○ blurred vision ○ increased sensitivity to sunlight ○ taste disturbances	

Serious side effects

The below list includes serious to very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Serious side effects	What to do
● 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. ● watery and severe diarrhoea ● swelling of the face, lips, tongue or throat, which may cause difficulty breathing ● yellowing of the skin or eyes, especially if accompanied by fever, fatigue, loss of appetite, dark coloured urine or light coloured bowel movements ● pain in the kidney region ● swelling of the 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 ● severe blisters and bleeding in the lips, eyes, mouth, nose or genitals (Stevens-Johnson syndrome) ● sudden or severe hives or itchy skin which may be accompanied by fever ● 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	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.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell, when taking, or soon after finishing taking ZOPRAL or ZOPRAL ODT.

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

Low levels of magnesium in blood level may occur if you take this medicine for more than three months. Your doctor may want to take some blood tests from time to time to check your progress.

Other problems are more likely to arise from the ulcer itself rather than the treatment.

For this reason, tell your doctor immediately if you notice any of the following:

- pain or indigestion occurring during treatment with ZOPRAL or ZOPRAL ODT
- vomiting blood or food
- passing of black (blood-stained) bowel 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 ZOPRAL contains

Active ingredient (main ingredient)	lansoprazole 15 mg or 30 mg per capsule
Other ingredients (inactive ingredients)	● Sugar spheres ● magnesium carbonate hydrate ● sucrose ● maize starch ● hypolose ● methacrylic acid copolymer ● purified talc ● macrogol 6000 ● titanium dioxide ● polysorbate 80 ● colloidal anhydrous silica ● Empty Hard Gelatin Capsule Size 2 Green Op/Green Op G2HCSA00735 [15 mg capsule only] (ARTG PI No.: 107737) ● Empty Hard Gelatin Capsule Size 0 Pink Op/Pink Op G0HCSA01082 [30 mg

	capsule only] (ARTG PI No.: 107738) • Tek Print SW-9009 Black Ink (ARTG PI No.: 2343)
Potential allergens	galactose, phenylalanine, sugars and sulfites

What ZOPRAL ODT contains

Active ingredient (main ingredient)	lansoprazole 15 mg or 30 mg per orally disintegrating tablet
Other ingredients (inactive ingredients)	• magnesium carbonate hydrate • sugar spheres (sucrose & maize starch) • crospovidone • hypromellose • methacrylic acid - ethyl acrylate copolymer (1:1) • triethyl citrate • sodium hydroxide • purified talc • polysorbate 80 • macrogol 6000 • iron oxide red • iron oxide yellow • mannitol • microcrystalline cellulose • sodium starch glycolate type A • aspartame • sodium lauryl sulphate • sodium bicarbonate • citric acid monohydrate • magnesium stearate • Strawberry 052311 AP0551(flavour) (ARTG PI No.: 105990).
Potential allergens	aspartame, phenylalanine and sulfites

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

What ZOPRAL & ZOPRAL ODT looks like

ZOPRAL 15 mg is white to off-white coloured pellets filled in a hard gelatin capsule with green opaque cap and green opaque body imprinted with 'MYLAN' over '8015' on both cap and body with black ink (AUST R 166764).

ZOPRAL 30 mg is white to off-white coloured pellets filled in a hard gelatin capsule with pink opaque cap and pink opaque body imprinted with 'MYLAN' over '8030' on both cap and body with black ink (AUST R 166765).

ZOPRAL ODT 15 mg is white to yellowish white round, flat-faced beveled edged tablet engraved with "LP1" on one

side and "M" on other side with orange to dark brown speckles (AUST R 187430).

ZOPRAL ODT 30 mg is white to yellowish white round, flat-faced beveled edged tablet engraved with "LP2" on one side and "M" on other side with orange to dark brown speckles (AUST R 187431).

Available in blister packs of 28 capsules.

Who distributes ZOPRAL & ZOPRAL ODT

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

This leaflet was prepared in May 2024.

ZOPRAL® is a Viatris company trade mark

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