

## 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 using Ozpan?

Ozpan contains the active ingredient pantoprazole. Ozpan is used to treat and help heal duodenal and gastric ulcers, treat reflux oesophagitis or reflux disease and treat Zollinger-Ellison syndrome.

For more information, see Section [1. Why am I using Ozpan?](#) in the full CMI.

### 2. What should I know before I use Ozpan?

Do not use if you have ever had an allergic reaction to Ozpan 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 use Ozpan?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Ozpan 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 use Ozpan?

- The usual dose is 40 mg per day.
- Your doctor will prescribe the dose that is right for you.
- Swallow your tablets whole with a little water with or without food.

More instructions can be found in Section [4. How do I use Ozpan?](#) in the full CMI.

### 5. What should I know while using Ozpan?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Ozpan.</li><li>• Tell your doctor immediately if you become pregnant while you are taking Ozpan.</li><li>• If you are about to have any blood tests, tell your doctor that you are taking this medicine.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not use Ozpan to treat any other complaints unless your doctor tells you to.</li><li>• Do not give Ozpan to anyone else, even if they have the same symptoms as you.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how Ozpan affects you.</li><li>• This medicine is not expected to affect your ability to drive a car or operate machinery. However, do not drive a car or operate machines if you experience side effects such as dizziness or blurred vision.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep Ozpan tablets in a cool dry place where the temperature stays below 25°C.</li></ul>

For more information, see Section [5. What should I know while using Ozpan?](#) in the full CMI.

### 6. Are there any side effects?

Some of the common side effects include: headache, dizziness, diarrhea, nausea or vomiting, stomach pain, excessive gas in the stomach or bowel.

Some of the serious side effects include and may require urgent attention: unusual tiredness or weakness, dark coloured urine, blood in the urine, increased or decreased need to urinate, skin problems such as itchiness, redness, rash with swelling, blistering or peeling of the skin or rash when exposed to the sun, possibly with pain in the joints and general fever.

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.

# Ozpan

Active ingredient(s): *pantoprazole*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Ozpan. **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 Ozpan.**

**Where to find information in this leaflet:**

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

## 1. Why am I using Ozpan?

**Ozpan contains the active ingredient pantoprazole.**

Ozpan belongs to a group of medicines called proton pump inhibitors (PPIs).

**Ozpan is used to treat and help heal duodenal and gastric ulcers.**

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.

Most people who have a peptic ulcer also have bacteria called *Helicobacter pylori* in their stomach. When Ozpan is taken with antibiotics the combination therapy will kill the *Helicobacter pylori* and let your ulcer heal.

Ozpan may also be used to prevent ulcers associated with the use of non-steroidal anti-inflammatory drugs (NSAIDs). These are medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis (inflammation of the joints).

**Ozpan is also used to treat reflux oesophagitis or reflux disease. This can be caused by “washing back” (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 heartburn.

Ozpan is also used to prevent reflux oesophagitis from coming back.

**Ozpan is used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces very large**

**amounts of acid, much more than in ulcers and reflux disease.**

This medicine works by decreasing the amount of acid the stomach makes, to give relief from the symptoms and allow healing to take place.

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

Your doctor may have prescribed Ozpan for another reason.

This medicine is not addictive.

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

## 2. What should I know before I use Ozpan?

### Warnings

**Do not use Ozpan if:**

- you are allergic to pantoprazole, or any of the ingredients listed at the end of this leaflet. Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.
- Always check the ingredients to make sure you can use this medicine.
- **Do not take this medicine if you have severe liver disease or cirrhosis.**
- Do not take Ozpan in combination with antibiotics or any other medicine if:
  - you are allergic to any of the antibiotics or medicines your doctor may prescribe with Ozpan
  - you have moderate to severe liver or kidney disease
- Do not take Ozpan in combination with atazanavir or nelfinavir (an anti-viral medication).
- Do not take Ozpan if the packaging is torn or shows signs of tampering.
- Do not take Ozpan after the expiry date (EXP) printed on the pack has passed. If it has expired or is damaged return it to your pharmacist for disposal.

**Check with your doctor if you:**

- have any other medical conditions: moderate to severe liver or kidney disease
- take any medicines for any other condition
- Tell your doctor if you have any of the following symptoms:
  - unintentional weight loss
  - repeated vomiting
  - difficulty or pain when swallowing
  - you look pale and feel weak
  - you notice blood in your stools

Your doctor may need to perform some additional tests before you take Ozpan.

- Tell your doctor or pharmacist if you have any allergies to any other medicines, foods, preservatives or dyes.
- Tell your doctor if you have or have had any other medical conditions.
- Your doctor can discuss the risks and benefits involved. If you have not told your doctor about any of the above, tell them before you take Ozpan.

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.

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

### Use in children

Ozpan should not be given to children.

There is not enough information to recommend the use of this medicine for children.

## 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 Ozpan and affect how it works.

These may include:

- warfarin, phenprocoumon (medicines used to prevent blood clots anticoagulants)
- atazanavir, nelfinavir – medicines used to treat viral infections such as HIV
- ketoconazole, itraconazole, posaconazole – medicines used to treat fungal infection
- methotrexate – a medicine used to treat arthritis and some types of cancer
- erlotinib or related medicines used to treat cancer
- tacrolimus, mycophenolate mofetil – medicines used to suppress the immune system
- fluvoxamine – a medicine used to treat anxiety and depression

These medicines may be affected by Ozpan, or may affect how well it works. You may need to use different amounts of your medicine, or 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 Ozpan.**

## 4. How do I use Ozpan?

### How much to take

- The usual dose is 40 mg per day.
- However, if your doctor also prescribes antibiotics in combination with Ozpan for the treatment of duodenal ulcers, the dose of Ozpan should be taken in the morning and the second should be taken before the evening meal for 7 days.
- Your doctor will prescribe the dose that is right for you.
- The dose and frequency of Ozpan that your doctor prescribes for you depends on your medical condition.
- Your doctor may change the dose as your condition changes.
- Follow the instructions provided and use Ozpan until your doctor tells you to stop.

### How to take it

- Swallow your tablets whole with a little water with or without food.

### When to take Ozpan

- Take Ozpan 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 to remember when to take it.

If you are taking other medicines, like antibiotics, in combination with Ozpan therapy, follow the instructions for use of each medicine carefully.

**Do not crush or chew the tablets. Ozpan tablets have a special coating to protect them from the acidic contents of your stomach. For Ozpan to work effectively, this coating must not be broken.**

### How long to take it

- Continue taking your medicine for as long as your doctor or pharmacist tells you.

### If you forget to use Ozpan

**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 trouble remembering to take your medicine, ask your pharmacist for some hints.

## If you use too much Ozpan

If you think that you have used too much Ozpan, 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 using Ozpan?

### Things you should do

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

Remind any doctor, dentist or pharmacist you visit that you are using Ozpan.

If you are going to have surgery, tell the surgeon that you are taking this medicine.

Tell your doctor immediately if you become pregnant while you are taking Ozpan.

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

It may interfere with the results of some tests.

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

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

### Things you should not do

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

Do not give Ozpan to anyone else, even if they have the same symptoms as you.

### Things that may help your condition

Some self help measures suggested below may help your condition. Your doctor or pharmacist can give you more information about these measures.

- Alcohol - your doctor may advise you to limit your alcohol intake.
- Aspirin and many other medicines used to treat arthritis, period pain, 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.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Ozpan affects you.**

This medicine is not expected to affect your ability to drive a car or operate machinery.

However, do not drive a car or operate machines if you experience side effects such as dizziness or blurred vision.

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

### 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 Ozpan tablets 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.

Heat and dampness can destroy some medicines.

**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 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.

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

It helps most people peptic ulcers or reflux disease, but it may have unwanted side effects in a few people.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• headache</li> <li>• dizziness</li> <li>• diarrhoea</li> <li>• nausea or vomiting</li> <li>• stomach pain</li> <li>• excessive gas in the stomach or bowel</li> <li>• indigestion</li> <li>• constipation</li> <li>• dry mouth</li> <li>• metallic taste</li> <li>• weakness or tiredness</li> <li>• increased sweating or body temperature</li> <li>• blurred vision</li> <li>• skin problems such as itchiness and rash</li> <li>• trouble sleeping</li> </ul> <p>These are the more common side effects of Ozpan.</p>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• unusual tiredness or weakness</li> <li>• nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine</li> <li>• blood in the urine</li> <li>• increased or decreased need to urinate</li> <li>• skin problems such as itchiness, redness, rash with swelling, blistering or peeling of the skin or rash when exposed to the sun, possibly with pain in the joints and general fever</li> <li>• swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing</li> <li>• frequent infections such as fever, severe chills, sore throat or mouth ulcers</li> <li>• chest pain</li> <li>• shortness of breath</li> <li>• high blood pressure</li> <li>• water retention, swelling</li> </ul>	<p><b>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.</b></p>

<ul style="list-style-type: none"> <li>• bleeding or bruising more easily than normal</li> <li>• depression, confusion or anxiety</li> <li>• bone fracture of the hip, wrist or spine (mainly a risk in people who take high doses of PPIs or use them long term (a year or longer))</li> <li>• symptoms such as seizures, abnormal or fast heartbeat or jerking/shaking movements. These can be sign of low magnesium, calcium or potassium levels in your blood</li> <li>• severe and/or persistent diarrhoea, because this medicine has been associated with a small increase in infectious diarrhea</li> </ul> <p>The above list includes serious side effects that may require urgent medical attention. Serious side effects are rare.</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.

Ask your doctor or pharmacist if you do not understand anything in this list.

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

### 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](http://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 Ozpan contains

<b>Active ingredient (main ingredient)</b>	pantoprazole
<b>Other ingredients (inactive ingredients)</b>	sodium carbonate, mannitol, crospovidone, hypolose, microcrystalline cellulose, calcium stearate, Opadry

	02H52369 yellow, methacrylic acid – ethyl acrylate copolymer (1:1), triethyl citrate, sodium lauryl sulfate, titanium dioxide, iron oxide yellow, purified talc, Opacode S-1-17823 black.
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**Do not take this medicine if you are allergic to any of these ingredients.**

**What Ozpan looks like**

Ozpan 20 mg and 40 mg tablets are available packs of 30 tablets.

Ozpan 20 mg are yellow, enteric-coated oval-shaped, biconvex tablets imprinted with ‘II’ on one side and plain on other side. (AUST R 151290)

Ozpan 40 mg are yellow, enteric-coated oval-shaped, biconvex tablets imprinted with ‘IV’ on one side and plain on other side. (AUST R 151291)

**Who distributes Ozpan**

Ozpan tablets are supplied in Australia by:  
Sun Pharma ANZ Pty. Ltd  
Macquarie Park NSW 2113  
Australia  
[customerservice.aus@sunpharma.com](mailto:customerservice.aus@sunpharma.com)  
Tel: 1800 726 229

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