

# OZPAN

*Pantoprazole enteric-coated tablets*

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## Consumer Medicine Information

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### What is in this leaflet

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This leaflet answers some common questions about **OZPAN (Pantoprazole enteric-coated tablets 20/40 mg)**.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet.

More recent information may be available. The latest Consumer Medicine Information is available from <https://www.ebs.tga.gov.au/> and may contain important information about the medicine and its use of which you should be aware.

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

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

**Keep this leaflet with the medicine.**

You may need to read it again.

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### What OZPAN is used for

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The name of your medicine is **OZPAN**. It contains the active ingredient pantoprazole.

#### Ulcers

**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).

#### Reflux disease

**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.

#### Zollinger-Ellison syndrome

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

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.

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.**

**OZPAN should not be given to children.**

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

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### Before you take OZPAN

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*When you must not take it*

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

- pantoprazole
- 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.

**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.

*Before you start to take it*

**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.**

**Tell your doctor if you are pregnant, intend to become pregnant, are breast-feeding or intend to breast-feed.**

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.

*Taking other medicines*

**Tell your doctor if you are taking any other medicines, including medicines that you buy without a**

**prescription from your pharmacy, supermarket or health food shop.**

Some medicines may be affected by **OZPAN**, or may affect how well 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.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking **OZPAN**.

**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**.

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## How to take OZPAN

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

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.**

*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.

*How to take it*

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

*When to take it*

**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 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 that 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 take too much (overdose)*

**Immediately telephone your doctor or Poisons Information Centre for advice - the telephone number in Australia is 13 11 26 or go to Accident and Emergency (Casualty) at your nearest hospital, if you think that you or anyone else may have taken too much OZPAN. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers for these places handy.**

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## While you are taking OZPAN

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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 OZPAN.**

**Tell any other doctors, dentists and pharmacists who are treating you that you are taking 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 must 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.

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## Side effects

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**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.

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. You may need medical attention if you get some of the side-effects.

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

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

- headache
- dizziness
- diarrhoea
- nausea or vomiting
- stomach pain
- excessive gas in the stomach or bowel
- indigestion
- constipation
- dry mouth
- metallic taste
- weakness or tiredness
- increased sweating or body temperature
- blurred vision
- skin problems such as itchiness and rash
- trouble sleeping

These are the more common side effects of OZPAN.

**Tell your doctor immediately if you notice any of the following:**

- unusual tiredness or weakness

- nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine.
- blood in the urine
- increased or decreased need to urinate
- skin problems such as itchiness and rash, with swelling, blistering or peeling of the skin or rash when exposed to the sun, possibly with pain in the joints.
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- chest pain
- shortness of breath
- high blood pressure
- water retention, swelling
- bleeding or bruising more easily than normal
- depression, confusion or anxiety
- 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))
- symptoms such as seizures, abnormal or fast heartbeat or jerking/shaking movements. These can be sign of low magnesium levels in your blood
- severe and/or persistent diarrhoea, because this medicine has been associated with a small increase in infectious diarrhoea

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

**Tell your doctor if you notice anything else that is making you feel unwell. Other side effects not listed above 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.

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## After taking OZPAN

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### Storage

**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.

**Do not store OZPAN or any other medicines in a bathroom or near a sink. Do not leave it in the car or on window sills.**

Heat and dampness can destroy some medicines.

**Keep OZPAN 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 **OZPAN** or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

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## Product Description

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### What OZPAN looks like

**OZPAN** 20 mg and 40 mg tablets are available packs of 30 tablets.

**OZPAN** 20 mg are yellow, enteric-coated ovalshaped, biconvex tablets imprinted with ‘II’ on one side and plain on other side.

**OZPAN** 40 mg are yellow, enteric-coated ovalshaped, biconvex tablets imprinted with ‘IV’ on one side and plain on other side.

## Ingredients

### Active ingredient

**OZPAN** 20 mg tablets contains the equivalent of 20 mg of pantoprazole.

**OZPAN** 40 mg tablets contains the equivalent of 40 mg of pantoprazole.

### Inactive ingredients

**OZPAN** contains the following inactive ingredients: 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.

### Australian Registration Numbers

**OZPAN** 20 mg tablets: AUST R 151290

**OZPAN** 40 mg tablets: AUST R 151291

### Sponsor

**OZPAN** tablets are supplied in Australia by:

Sun Pharma ANZ Pty. Ltd  
Macquarie Park NSW 2113  
Australia

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