

Ozmep Enteric-coated Tablets

contains the active ingredient omeprazole

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Ozmep.

It does not contain all of 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 Ozmep 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 Ozmep is used for

Peptic Ulcers

Ozmep tablets are used to treat peptic ulcers and also to help prevent them from coming back.

These ulcers can be caused by the stomach producing too much acid. Depending on the location of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach and a duodenal ulcer occurs in the tube leading out of the stomach, also known as the duodenum.

Peptic Ulcers associated with *Helicobacter pylori* infection

Most people with a peptic ulcer have been found to have the bacteria *Helicobacter pylori* in their stomach. Ozmep taken together with two antibiotics will kill the bacteria and let your ulcer heal. It is

possible that the antibiotics may not always kill *Helicobacter pylori*.

Peptic Ulcers associated with Non-steroidal Anti-inflammatory Drugs (NSAIDs)

Some peptic ulcers are caused by taking medicines known as non-steroidal anti-inflammatory drugs. These medicines are commonly taken to treat arthritis and other inflammatory conditions.

Ozmep can be used to heal and prevent ulcers associated with NSAIDs.

Reflux Oesophagitis

Ozmep is used to treat and prevent the symptoms of reflux oesophagitis.

This condition is caused by the washing back, or reflux, of food and acid from the stomach into the oesophagus. Symptoms include a burning sensation in the chest rising up to the throat, also known as heartburn.

Zollinger-Ellison Syndrome

Ozmep is used to treat this rare condition where the stomach produces excessive amounts of acid.

How Ozmep works

Ozmep belongs to a group of medicines called proton pump inhibitors. These medicines work by decreasing the amount of acid made by the stomach, to give relief from the symptoms and allow healing to take place. This does not stop food from being digested in the normal way.

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

Your doctor may have prescribed Ozmep for another reason.

Ozmep is available only with a doctor's prescription.

There is no evidence that Ozmep is addictive.

Before you take Ozmep

When you must not take it

Do not take Ozmep if you are allergic to:

- omeprazole or any of the ingredients listed at the end of this leaflet
- any medicine containing a proton-pump inhibitor

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

Do not take Ozmep if you are also taking a medicine containing cilostazol.

Please check with your doctor or pharmacist if you are taking cilostazol. This medicine will be affected by Ozmep.

Do not take Ozmep if the expiry date (Exp.) printed on the pack has passed.

Do not take Ozmep if the packaging shows signs of tampering or the tablets do not look quite right.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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

Ozmep may affect your unborn baby if taken during pregnancy. Your doctor will discuss the risks and benefits of taking Ozmep during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

It is not known whether Ozmep passes into breast milk. Your doctor will discuss the risks and benefits of taking Ozmep when breastfeeding.

Tell your doctor if you have any problems with your liver.

Tell your doctor if you have been diagnosed with osteoporosis

Tell your doctor if you have ever had a skin reaction after treatment with a medicine similar to Ozmep that reduces stomach acid.

Tell your doctor if you have, or have had, any other medical conditions.

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

Taking other medicines

Do not take Ozmep if you are taking the following medicine:

- cilastazol, a medicine used to treat intermittent claudication

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

Some medicines may be affected by Ozmep, or may affect how well it works. These include:

- phenytoin, a medicine used to treat epilepsy or fits
- methotrexate- a medicine used to treat arthritis and some types of cancer
- warfarin and clopidogrel, a medicine used to prevent blood clots
- digoxin, a medicine used to treat heart conditions

- diazepam , a medicine used to treat anxiety and some other conditions
- St John’s wort, a herbal remedy used to treat mood disorders
- ketoconazole, itraconazole or voriconazole, medicines used to treat certain fungal infections
- medicines to treat infections, such as clarithromycin or rifampicin
- anti-viral medicines such as atazanavir and nelfinavir, used to treat infections such as HIV
- tacrolimus and mycophenolate, immunosuppressants, medicines used to assist in organ transplants
- erlotinib or related medicines used to treat cancer

These medicines may be affected by Ozmep 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 can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

How to take Ozmep

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

They may differ from the information in this leaflet.

How much to take

Adults:

The usual dose is 20 mg a day, but may vary from 10 mg to 40 mg a day depending on your condition and whether or not you are taking

any other medicines. Your doctor will advise you how much to take.

Children 1 year or older:

The usual dose for children 10 kg to 20 kg is 10 mg a day. This dose may be increased to 20 mg if required. For children more than 20 kg the dose is 20 mg a day which may be increased to 40 mg if required.

Ask your doctor or pharmacist if you are not sure how to take Ozmep.

How to take Ozmep

Swallow the tablets whole with a glass of water. Do not crush or chew the tablets.

If the tablets are crushed or chewed they will not work properly.

When to take Ozmep

Ozmep can be taken with or without food.

Take Ozmep tablets at about the same time each day.

Keeping a regular time for taking tablets will help to remind you to take them.

If you forget to take Ozmep

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 tablets as you would normally.

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

If you are not sure what to do, ask your doctor or pharmacist.

How long to take Ozmep for

Keep taking Ozmep for as long as your doctor recommends.

In most patients, Ozmep relieves symptoms rapidly and healing is usually complete within 4 weeks.

If you take too much OzmeP (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) if you think you or anyone else may have taken too much OzmeP. Do this even if there are no signs of discomfort or poisoning.

If you take too much OzmeP you may experience nausea, vomiting, dizziness, abdominal pain, diarrhoea and headache.

While you are taking OzmeP

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking OzmeP.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking OzmeP.

If you become pregnant while taking OzmeP, tell your doctor.

Tell your doctor if your symptoms return.

Although OzmeP heals ulcers very successfully, it may not prevent them recurring at a later date.

If you need to have any medical tests while you are taking OzmeP, tell your doctor.

OzmeP may affect the results of some tests.

Things you must not do

Do not use OzmeP to treat any other conditions unless your doctor tells you to.

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

Do not stop taking your medicine or change the dose without checking with your doctor.

If you stop taking it suddenly or change the dose, your condition may worsen or you may have unwanted side effects.

Side effects

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

OzmeP helps most people with peptic ulcers or reflux disease, and is usually well tolerated, 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 treatment 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:

- diarrhoea
- constipation
- stomach pain
- nausea or vomiting
- dry or sore mouth
- flatulence
- skin rash, itchy skin
- headache
- dizziness

These side effects are usually mild.

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

- muscle pain or weakness, joint pain
- tingling or numbness of the hands or feet
- changes in sleep patterns
- mood changes, confusion or depression
- blurred vision
- increase in breast size (males)
- fever
- increased bruising
- increased sweating
- hair loss

- tremor
- pain or indigestion that occurs during treatment with OzmeP.
- vomiting blood or food
- blood in your stool (a dark black stool can be an indicator of this)
- low magnesium blood levels may cause decrease of potassium or calcium levels in blood
- involuntary muscle contraction, disorientation, convulsions, dizziness or increased heart rate caused by decrease in magnesium which may occur if you have been taking OzmeP for a period of 3 or more months.
- needing to urinate more frequently, lower back pain, fatigue can be signs of inflammation in your kidney.

These are serious side effects that may require medical attention. Serious side effects are rare.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- skin reaction which may include rash, redness, blistering or peeling of the skin
- ulcers, blisters or bleeding of the lips, eyes, mouth, nose and genitals
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- swelling of hands, feet or ankles
- shortness of breath or difficulty in breathing
- blood in the urine
- signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite
- skin reaction, especially in sun exposed areas, with joint pain

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

Occasionally, Ozmep may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

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

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

- pain or indigestion occurring during treatment with Ozmep
- vomiting of blood or food
- passing of black (blood-stained) motions.

After taking Ozmep

Storage

Keep Ozmep 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.

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

Do not store Ozmep or any other medicine in the bathroom or near a sink.

Do not leave Ozmep in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Ozmep, or your tablets have passed their expiry date, ask

your pharmacist what to do with any that are left over.

Product description

What it looks like

Ozmep tablets are brown capsule-shaped tablets.

Each bottle or blister contains 30 tablets.

Ingredients

The active ingredient in Ozmep is omeprazole. Each Ozmep tablet contains 20 mg of omeprazole.

The tablets also contain:

- lactose monohydrate
- sodium starch glycollate
- sodium stearate
- sodium stearyl fumarate
- hypromellose acetate succinate
- triethyl citrate
- sodium lauryl sulfate
- carnauba wax
- purified talc
- monoethanolamine
- propylene glycol
- hypromellose
- titanium dioxide
- iron oxide yellow
- iron oxide red

Supplier

Sponsor

Medis Pharma Pty Ltd
Level 1, 37 Epping Road
Macquarie Park, NSW 2113
Australia

Distributor

Arrotex Pharmaceuticals
15-17 Chapel Street
Cremorne, VIC 3121
Australia

Australian registration number:

Blister pack

AUST R 149348

Bottle

AUST R 188822

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