

APO-Omeprazole

Contains the active ingredient, omeprazole

Consumer Medicine Information

For a copy of a large print leaflet, ph 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine. Ask your doctor or pharmacist if you do not understand anything or are worried about taking your medicine.

This leaflet answers some common questions about omeprazole.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. Some more recent information on your medicine may be available. Speak to your pharmacist or doctor to obtain the most up-to-date information.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Keep this leaflet with your medicine.

You may want to read it again.

What omeprazole is used for

The name of your medicine is APO-Omeprazole. It contains the active ingredient, omeprazole.

It is used to treat the following conditions:

- **Reflux Oesophagitis**

Omeprazole is used to treat the symptoms of reflux oesophagitis or reflux disease. This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe (oesophagus).

Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.

Omeprazole is also used to help stop reflux oesophagitis coming back or relapsing.

- **Peptic Ulcers**

Omeprazole is used to treat peptic 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 from the stomach.

These ulcers can be caused by too much acid being made in the stomach.

Omeprazole is also used to help stop peptic or duodenal ulcers coming back.

- **Peptic Ulcers Associated with Helicobacter pylori Infection**

Helicobacter pylori is a bacteria that often occurs in the stomach together with peptic ulcers.

When omeprazole is taken together with an antibiotic, they work together to kill the bacteria and let your ulcer heal. You may

need further treatment with antibiotics.

- **Peptic Ulcers Associated with Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)**

Some peptic ulcers are caused by taking medicines called non-steroidal anti-inflammatory drugs (NSAIDs), a type of medicine used to treat pain, swelling or inflammation, including arthritis and joint pain.

Omeprazole is used to treat and help to prevent ulcers developing, which are associated with long-term use of NSAIDs.

- **Zollinger-Ellison Syndrome**

Omeprazole is also used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces large amounts of acid, much more than in ulcers or reflux disease.

How it works

Omeprazole belongs to a group of medicines called proton-pump inhibitors.

It works by decreasing the amount of acid made by the stomach, to give relief of symptoms and allow healing to take place. This does not stop food being digested in the normal way.

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

Your doctor may have prescribed omeprazole for another reason.

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

There is no evidence that this medicine is addictive.

Use in children

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

Before you take omeprazole

When you must not take it

Do not take this medicine if you have had an allergic reaction to omeprazole, any medicine containing a proton-pump inhibitor (e.g. esomeprazole, lansoprazole, pantoprazole, rabeprazole) or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; muscle pain or tenderness or joint pain or rash, itching or hives on the skin.

Do not take this medicine after the expiry date (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take this medicine if the packaging is torn, shows signs of tampering or if it does not look quite right.

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 or pharmacist.

Before you start to take it

Tell your doctor if you:

1. have allergies to:

- any other medicines

- any other substances, such as foods, preservatives or dyes.
- 2. have or have had any medical conditions, especially the following:**
- any problems with your liver.
- 3. are pregnant or plan to become pregnant.**

It is not known if it is safe for you to take omeprazole while you are pregnant. It may affect your baby.

4. you are breast-feeding or plan to breast-feed.

It is not known if your baby can take in omeprazole from breast milk, if you are breast-feeding. Breast-feeding is not recommended if you are taking omeprazole.

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

Taking other medicines

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

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

- phenytoin - a medicine used to treat epilepsy or fits
- warfarin - a medicine used to prevent blood clots
- diazepam - a medicine used to treat anxiety and some other conditions
- ketoconazole, itraconazole, voriconazole - medicines used to treat fungal infection
- clarithromycin - a medicine used to treat bacterial infections
- atazanavir and nelfinavir - medicines used to treat viral infections, such as HIV
- tacrolimus - a medicine used to assist in organ transplants.

- clopidogrel - is used to prevent blood clots forming in hardened blood vessels.

These medicines may be affected by omeprazole 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 can tell you if you are taking any of these medicines. They may also have more information on medicines to be careful with or avoid while taking omeprazole.

Other interactions not listed above may also occur.

How to take this medicine

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

They may be different to the information in this leaflet.

If you do not understand any written instructions, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how many tablets you will need to take. This depends on your condition and whether or not you are taking any other medicines.

Adults:

The dose is usually 20 mg a day. The dose may vary from 10 mg to 40 mg a day depending on what condition you are being treated for and how severe it is.

How to take it

Swallow the tablets whole with a glass of water.

Do not crush or chew the tablets.

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

When to take it

Take it at about the same time each day.

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

It does not matter if you take it before, with or after food.

How long to take it for

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

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

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 your medicine 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 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.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 for Australia) for advice, or go to the Accident and Emergency Department at the nearest hospital, if you think that you or anyone else may have taken too much omeprazole.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much omeprazole, you may get nausea, vomiting,

dizziness, stomach pain, diarrhoea, headache.

While you are taking omeprazole

Things you must do

Take this medicine exactly as your doctor has prescribed.

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

Tell your doctor immediately if you become pregnant.

Tell your doctor if your symptoms return.

Although omeprazole can heal ulcers successfully, it may not prevent them coming back at a later date.

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

Go to your doctor regularly for a check-up.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not take your medicine to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop taking your medicine, or change the dosage, 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.

Things to be careful of

Be careful while driving or operating machinery until you know how omeprazole affects you.

Omeprazole generally does not cause any problems with your ability to drive a car or operate machinery.

However, as with many other medicines, omeprazole may cause dizziness in some people. Make sure you know how you react to omeprazole before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy. If you drink alcohol, dizziness may be worse.

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.

- **Alcohol -**
your doctor may advise you to limit your alcohol intake.
- **Aspirin and similar medicines used to treat arthritis, period pain or headaches -**
these medicines may irritate your stomach and make your condition worse. Your doctor or pharmacist can 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 -**
if you are overweight, your doctor may suggest losing some weight to help your condition.

Side effects of omeprazole

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time, they are not.

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

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

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

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

- constipation
- nausea/vomiting
- flatulence (wind)
- stomach pain
- diarrhoea
- headache
- skin rash.

The above list includes the more common side effects (except skin rash). Mostly, these are mild.

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

- muscle pain, joint pain or weakness
- dizziness
- "pins and needles" (tingling or numbness) in the hands and feet
- changes in sleep patterns
- mood changes
- increase in breast size (males)
- fever
- signs of liver inflammation including yellowing of the skin or eyes, generally feeling unwell, nausea, vomiting, loss of appetite.
- increased bruising, or bleeding more easily.

These may be serious side effects. You may need medical attention. Most of these side effects are rare.

If any of the following happen, stop taking your medicine and either tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth, tongue or throat, which may cause difficulty in breathing
- shortness of breath or difficulty breathing
- skin reaction, which may include rash, itching, redness, blistering or peeling of the skin
- swelling of feet, hands and ankles
- ulcers, blisters or bleeding of the lips, eyes, mouth, nose and genitals.

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

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

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

Other health problems may arise from the ulcer itself, rather than from omeprazole treatment. For this reason, contact your doctor immediately if you notice any of the following:

- stomach pain or indigestion during treatment with omeprazole
- passing black or blood-stained motions.
- vomiting blood or food.

After taking this medicine

Storage

Keep your medicine in its original packaging until it is time to take them.

If you take the tablets out of their original packaging they may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25 degrees C.

- **Do not store your medicine, or any other medicine, in the bathroom or near a sink.**
- **Do not leave it on a window sill or in the car.**

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 or pharmacist tells you to stop taking this medicine or it has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

Product description

What APO-Omeprazole looks like

20 mg tablets:

Red brown, oblong, enteric-coated tablets.

Available in:

Bottles and blister packs of 30

Ingredients

Each tablet contains 20 mg of omeprazole as the active ingredient.

It also contains the following inactive ingredients:

- ascorbyl palmitate
- microcrystalline cellulose
- crospovidone
- magnesium stearate
- povidone
- lactose
- hypromellose phthalate
- glycerol triacetate
- purified talc
- iron oxide red
- iron oxide black.

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Omeprazole 20 mg tablets:

Bottles:

AUST R 147425

Blister packs:

AUST R 159732

Sponsor

Apotex Pty Ltd

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Australia

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