

OMEPRAZOLE GENERICHEALTH

(omeprazole) enteric-coated tablet

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Omeprazole generichealth. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Omeprazole generichealth against the benefits they expect it will 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.

What Omeprazole generichealth is used for

Peptic Ulcers

Omeprazole generichealth is 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. Omeprazole generichealth 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 nonsteroidal anti-inflammatory drugs. These medicines are commonly taken to treat arthritis and other inflammatory conditions.

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

Reflux Oesophagitis

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

Zollinger-Ellison Syndrome

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

How Omeprazole generichealth works

Omeprazole generichealth 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 this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

There is no evidence that Omeprazole generichealth is addictive.

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

Before you take Omeprazole generichealth

When you must not take it

Do not take Omeprazole generichealth if you have an allergy to:

- any medicine containing omeprazole;
- 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:

- 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.

Do not take Omeprazole generichealth 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 Omeprazole generichealth.

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

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- any problems with your liver;
- any other medical conditions;
- been diagnosed with osteoporosis;
- if you have ever had a skin reaction after treatment with a medicine similar to Omeprazole generichealth that reduces stomach acid.

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

It is not known if it is safe to take Omeprazole generichealth during pregnancy. It may affect your baby. Your doctor will discuss the risks and benefits of taking Omeprazole generichealth during pregnancy.

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

It is not known whether Omeprazole generichealth passes into breast milk. Your doctor will

discuss the risks and benefits of taking Omeprazole generichealth when breastfeeding.

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

Taking other medicines

Do not take Omeprazole generichealth if you are taking the following medicine:

- cilostazol, a medicine used to treat intermittent claudication.

It is not recommended that you take Omeprazole generichealth if you are taking atazanavir and nelfinavir, medicines (used to treat viral infections such as HIV).

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

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

- phenytoin, a medicine used to treat epilepsy or fits;
- 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, an herbal remedy used to treat mood disorders;
- ketoconazole, itraconazole or voriconazole, medicines used to treat certain fungal infections;
- clarithromycin or rifampicin, medicines used to treat infections;
- atazanavir and nelfinavir, medicines used to treat viral infections such as HIV as their use is not recommended (see above);

- tacrolimus and mycophenolate mofetil, medicines used to assist in organ transplants;
- methotrexate, a medicine used to treat arthritis and some types of cancer;
- erlotinib or related medicines used to treat cancer.

These medicines may be affected by Omeprazole generichealth 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 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 this medicine.

How to take Omeprazole generichealth

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, ask your doctor or pharmacist for help.

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 Omeprazole generichealth.

How to take it

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 it

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

Take your medicine at about the same time each day.

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

The tablets can be taken with food or on an empty stomach.

How long to take it

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

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

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 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 that you missed.

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 (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Omeprazole generichealth. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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

While you are taking Omeprazole generichealth

Things you must do

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

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking Omeprazole generichealth, tell your doctor.

Tell your doctor if your symptoms return.

Although Omeprazole generichealth 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 Omeprazole generichealth, tell your doctor.

Omeprazole generichealth may affect the results of some tests

Things you must not do

Do not take Omeprazole generichealth 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 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 Omeprazole generichealth.

This medicine helps most people with peptic ulcers or reflux disease, and is usually well tolerated, but it may have unwanted side effects in a few people.

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

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

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

Tell your doctor or pharmacist 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;
- weight gain;
- drowsiness;
- insomnia;
- changes in taste;

- tiredness.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

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

- muscle pain or weakness, joint pain;
- tingling, ‘pins and needles’ or numbness of the hands or feet
- fever
- changes in sleep patterns;
- mood changes, agitation, confusion, hallucinations or depression;
- hallucinations;
- blurred vision;
- increase in breast size (males);
- increased bruising or bleeding;
- increased sweating;
- hair loss;
- tremor;
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers;
- inability to get or maintain erection;
- fractures, for example hip, wrist or spine.

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

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

- severe 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, Omeprazole generichealth may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

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

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

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 Omeprazole generichealth;
- vomiting of blood or food;
- passing of black (bloodstained) motions.

Tell your doctor if your reflux symptoms return after you stop taking Omeprazole generichealth.

After taking Omeprazole generichealth

Storage

Keep your tablets in the pack/box until it is time to take them.

If you take the tablets out of the pack/box, they may not keep well.

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

Do not store Omeprazole generichealth 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 tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Omeprazole generichealth tablets are red brown, oblong, enteric coated tablets.

They are available in packs of 5, 10 and 30 tablets in aluminium/aluminium blisters or HDPE bottles of 30 tablets.

Ingredients

Active ingredient

Omeprazole generichealth contains 20 mg of omeprazole as the active ingredient.

Other ingredients

- ascorbyl palmitate;
- triacetin
- microcrystalline cellulose;
- crospovidone;
- magnesium stearate;
- povidone;
- lactose monohydrate;
- hypromellose phthalate;
- purified talc;
- iron oxide red;

- iron oxide black.

Australian Registration Numbers

AI Blister: AUST R 234175

HDPE Bottle: AUST R 234176

Distributor

Omeprazole generichealth is distributed in Australia by:

Generic Health Pty Ltd

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