

APO-Omeprazole Capsules

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

This leaflet answers some common questions about this medicine. 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 this medicine 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 this medicine is used for

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 taken 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 gastric or duodenal ulcers coming back.

Peptic Ulcers Associated with Helicobacter pylori Infection

Most people who have a peptic ulcer also have a bacterium called Helicobacter pylori in their stomach.

When omeprazole is taken with antibiotics, they work to kill the bacterium 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 or inflammation. Omeprazole is used to heal and prevent ulcers associated with NSAIDs.

Zollinger-Ellison Syndrome

Omeprazole is 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 this medicine for another reason.

There is no evidence that this medicine is addictive.

This medicine is available only with a doctor's prescription

Before you take this medicine

When you must not take it

Do not take omeprazole 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 this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy. Your doctor can discuss with you the risks and benefits involved.

Do not breastfeed if you are taking this medicine.

It is not known whether omeprazole passes into breast milk and there is a possibility that your baby may be affected. Your doctor can discuss with you the risks and benefits involved.

Do not take this medicine if you are also taking cilostazol.

Cilostazol will be affected by omeprazole. Please check with your doctor or pharmacist if you are unsure.

Do not take this medicine after the expiry date printed on the pack 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
- an osteoporosis diagnosis
- if you have ever had a skin reaction after treatment with a medicine similar to omeprazole that reduces stomach acid

- any other medical conditions

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

Your doctor can discuss with you the risks and benefits involved.

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

Taking other medicines

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

- cilostazol, used to treat intermittent claudication

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 this one may interfere with each other. These include:

- cilostazol, used to treat intermittent claudication
- phenytoin, used to treat epilepsy or fits
- warfarin and clopidogrel, used to prevent blood clots
- digoxin, used to treat heart conditions

- diazepam, used to treat anxiety and some other conditions
- St John's Wort, a herbal remedy used to treat mood disorders
- ketoconazole, itraconazole or voriconazole, used to treat fungal infections
- clarithromycin or rifampicin, antibiotics used to treat infections
- atazanavir or nelfinavir, used to treat viral infections such as HIV
- tacrolimus and mycophenolate mofetil, immunosuppressants used to assist in organ transplants
- methotrexate, used to treat arthritis and some types of cancer
- erlotinib or related medicines used to treat cancer

These medicines may be affected by omeprazole 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 and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

If you have not told your doctor about any of these medicines, tell them before you take this medicine.

How to take this medicine

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 label, ask your doctor or pharmacist for help.

How much to take

The dose for omeprazole varies from patient to patient. Your doctor will decide the right dose for you.

How to take it

Swallow the capsules with a glass of water.

Do not crush or chew the capsules.

If the granules or pellets contained in the capsules are crushed or chewed, they will not work properly.

When to take it

Take this medicine at the same time each day.

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

Omeprazole can be taken with food or on an empty stomach.

How long to take it for

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

If you are taking omeprazole to heal an ulcer or to treat reflux disease, you will usually need to take omeprazole for 4 to 8 weeks.

It is very important that you take the full course of omeprazole as prescribed by your doctor so that your condition is properly treated.

If you are taking omeprazole to stop an ulcer from coming back or to treat other conditions, your doctor will tell you how long you need to take the capsules.

If you forget to take it

If it is almost time to take 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 (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 of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking this medicine

Things you must do

Take this medicine exactly as your doctor has prescribed.

If you are about to start any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell all doctors, dentists and pharmacists who are treating you that you are taking this medicine.

If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.

Tell your doctor if your symptoms return.

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

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

It may interfere with the results of some tests.

Keep all 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 take this medicine 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 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.

Side effects

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

All medicines can have side effects. Sometimes they are serious but 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 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 if you notice any of the following and they worry you:

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

These side effects are usually mild.

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

- muscle pain or weakness, or joint pain

- pins and needles sensation
- changes in sleep patterns
- mood changes, confusion or depression
- blurred vision
- increase in breast size (males)
- fever
- increased bruising
- increased sweating
- hair loss
- tremor

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:

- skin reaction which may include rash, itching, redness, blistering or peeling of the skin
- ulcers, blisters or bleeding of the lips, eyes, mouth, nose and genitals
- blood in urine

- swelling of feet, hands and ankles
- signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting or loss of appetite
- symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin

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

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.

Some of these side effects, such as changes in your liver or blood, or lower levels of Vitamin B12, can only be found when your doctor does tests from time to time to check your progress.

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 that occurs during treatment with omeprazole
- you begin to vomit blood or food
- you pass black (blood-stained) motions

Tell your doctor if your symptoms return or become worse after you have stopped this medicine.

Storage and disposal

Storage

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

If you take your medicine out of its original packaging it may not keep well.

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

Do not store this 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 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 APO-Omeprazole Capsules looks like

APO-OMEPRAZOLE has an opaque yellow cap and body No. 2 hard gelatin capsule containing enteric coated off-white spherical microgranules. AUST R 149518. AUST R 167316.

Each bottle or carton (in blisters) contains 30 capsules.

Ingredients

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

It also contains the following inactive ingredients:

- sodium lauryl sulfate
- dibasic sodium phosphate
- hypromellose
- mannitol
- macrogol 6000

- purified talc
- polysorbate80
- titanium dioxide
- eudragit L30D-55
- maize starch
- sucrose
- gelatin
- quinoline yellow

Distributor

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

Australia

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