

## 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.

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. More recent information on this medicine may be available.

##### Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from [www.apotex.com.au](http://www.apotex.com.au).

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

#### What this medicine is used for

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

It is used to treat:

##### • 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.

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.

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

##### 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.

There is no evidence that this medicine is addictive.

##### Use in children

This medicine should not be used in children.

#### Before you take this medicine

##### When you must not take it

##### Do not take this medicine if:

- **You are taking a medication containing cilostazol.**
- **You are pregnant.**  
Omeprazole may affect your developing baby if you take it during pregnancy.
- **You are breast-feeding.**  
Omeprazole may pass into human breast milk.
- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.
- **You have had an allergic reaction to omeprazole or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include 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; fainting or hayfever-like symptoms.

**If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.**

##### Before you start to take it

##### Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
  - any other medicines
  - any other substances, such as foods, preservatives or dyes.

2. You have or have had any medical conditions, especially the following:

- any problems with your liver or its enzymes
- have experienced significant unintentional weight loss, recurring vomiting with or without blood, trouble swallowing or black faeces
- risk of osteoporosis.

3. You are currently pregnant or you plan to become pregnant.

Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

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

Do not take this medicine whilst breast-feeding until you and your doctor have discussed the risks and benefits involved.

5. You are planning to have surgery or an anaesthetic.

6. You are taking or are planning to take any other medicines.

This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with omeprazole. These include:

- phenytoin - a medicine used to treat epilepsy for fits
- warfarin - a medicine used to prevent blood clots
- clopidogrel - is used to prevent blood clots forming in hardened blood vessels
- diazepam - a medicine used to treat anxiety and other conditions
- St John's wort - a herbal remedy used to treat mood disorders
- ketoconazole, itraconazole, voriconazole - medicines used to treat fungal infection
- clarithromycin or rifampicin - medicines used to treat bacterial infections
- atazanavir and nelfinavir - medicines used to treat viral infections, such as HIV
- tacrolimus or mycophenolate mofetil - medicines used to assist in organ transplants
- digoxin - a medicine used to treat abnormal heart rhythms
- cilostazol - a blood thinner used to treat intermittent claudication and improve walking
- methotrexate - a medicine used to treat arthritis and some types of cancers
- erlotinib or related medicines - used to treat cancer.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with omeprazole.

#### How to take this medicine

Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.

##### How much to take

Your doctor or pharmacist will tell you how much of this medicine you should take.

The usual dose is 20 mg once 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. This may also depend whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

#### *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 and 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 to take your next dose, skip the missed dose and take your next dose at the usual time. 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 missed doses.**

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

#### *If you take too much (overdose)*

**If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.**

**Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

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#### **While you are taking this medicine**

##### *Things you must do*

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breast-feeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

**Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.**

##### *Things you must not do*

#### **Do not:**

- Give this medicine to anyone else, even if their symptoms seem similar to yours

- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

#### *Things to be careful of*

Be careful when driving or operating machinery until you know how this medicine affects you.

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#### **Possible side effects**

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

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

#### **Tell your doctor or pharmacist if you notice any of the following and they worry you.**

This list includes the more common side effects. Mostly, these are mild:

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

#### **Tell your doctor as soon as possible if you notice any of the following.**

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

- muscle pain, joint pain or weakness
- dizziness
- "pins and needles" (tingling or numbness) in the hands and feet
- changes in sleep patterns
- increased sweating
- hair loss
- mood changes, confusion or depression
- increase in breast size (males)
- fever, vomiting and abdominal cramps accompanied by diarrhoea with or without blood or mucus
- increased bruising, or bleeding more easily
- disturbance in vision or hearing.

#### **If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

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

- swelling of the face, lips, mouth, tongue or throat, which may cause difficulty in 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
- blood in urine
- signs of liver inflammation including yellowing of the skin or eyes, generally feeling unwell, nausea, vomiting, loss of appetite

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

#### *Allergic reactions*

**If you think you are having an allergic reaction to omeprazole, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

Symptoms of an allergic reaction may include some or all of the following:

- 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
- fainting
- hayfever-like symptoms.

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#### **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 will stay below 25°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 this medicine where children cannot reach it.**

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, your pharmacist can dispose of the remaining medicine safely.

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#### **Product description**

##### *What APO-Omeprazole looks like*

##### *New Formulation:*

20 mg omeprazole is a red brown, oblong, enteric coated tablet.

Blister packs and bottles of 30 tablets.

Not all pack types may be available.

##### *Old Formulation:*

20 mg omeprazole is a brown capsule-shaped, enteric coated tablet debossed with "20" on one side.

Blister packs and bottles of 30 tablets.

Not all pack types may be available.

##### *Ingredients*

##### *New Formulation:*

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.

**Old Formulation:**

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

It also contains the following inactive ingredients:

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

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

**Australian Registration Numbers**

**New Formulation:**

APO-Omeprazole 20 mg tablet (blister pack):  
AUST R 243812.

APO-Omeprazole 20 mg tablet (bottles): AUST  
R 243813.

**Old Formulation:**

APO-Omeprazole 20 mg tablet (blister pack):  
AUST R 190946.

APO-Omeprazole 20 mg tablet (bottles): AUST  
R 193617.

**Sponsor**

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