

APO-Omeprazole

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using APO-Omeprazole?

APO-Omeprazole contains the active ingredient Omeprazole. APO-Omeprazole is used to treat reflux oesophagitis, peptic ulcer, Zollinger Ellison syndrome.

For more information, see Section [1. Why am I using APO-Omeprazole?](#) in the full CMI.

2. What should I know before I use APO-Omeprazole?

Do not use if you have ever had an allergic reaction to omeprazole or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use APO-Omeprazole?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-Omeprazole and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use APO-Omeprazole?

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

More instructions can be found in Section [4. How do I use APO-Omeprazole?](#) in the full CMI.

5. What should I know while using APO-Omeprazole?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, or pharmacist you visit that you are using APO-Omeprazole.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly or change the dosage without checking with your doctor• Do not take Omeprazole 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.
Driving or using machines	<ul style="list-style-type: none">• No information available
Drinking alcohol	<ul style="list-style-type: none">• No information available
Looking after your medicine	<ul style="list-style-type: none">• Keep your medicine in its original packaging until it is time to take it.• Keep your medicine in a cool dry place where the temperature will stay below 25°C.

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

6. Are there any side effects?

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

APO-Omeprazole

Active ingredient(s): *Omeprazole*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-Omeprazole. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using APO-Omeprazole.**

Where to find information in this leaflet:

- [1. Why am I using APO-Omeprazole?](#)
- [2. What should I know before I use APO-Omeprazole?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use APO-Omeprazole?](#)
- [5. What should I know while using APO-Omeprazole?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using APO-Omeprazole?

APO-Omeprazole contains the active ingredient omeprazole. APO-Omeprazole belongs to group of medicines called proton-pump inhibitors.

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

Follow all directions given to you by your doctor carefully.

This may differ from the information contained in this leaflet. There is no evidence that this medicine is addictive

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 gastric 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.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

There is no evidence that this medicine is addictive.

Use in Children

This medicine should not be used in children.

2. What should I know before I use APO-Omeprazole?

Warnings

Do not use APO-Omeprazole 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.
- Always check the ingredients to make sure you can use this medicine.

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

Check with your doctor if you:

- have any other medical conditions [list any notable ones for the medicine / medical condition here]
- take any medicines for any other condition
- [insert specific precautions relevant to the medical condition].

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

Some medicines may interfere with APO-omeprazole and affect how it works.

- Phenytoin-a medicine used to treat epilepsy or fits
- Warfarin and clopidogrel-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, voriconazole - medicines used to treat fungal infection

- clarithromycin or rifampicin - medicines used to treat infections
- atazanavir and nelfinavir - medicines used to treat viral infections such as HIV
- 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 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 other 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 things, tell them before you take Omeprazole.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APO-Omeprazole.

4. How do I use APO-Omeprazole?

How much to take / use

- The usual dose is 20mg once a day. The dose may vary from 10mg 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 medicine.
- Follow the instructions provided and use APO-Omeprazole until your doctor tells you to stop.

Swallow Omeprazole 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.

If you have difficulty swallowing the tablets

1. Place the tablet in half a glass of non-carbonated water or fruit juice. Mineral water, carbonated fruit juice, or other liquids are not suitable.
2. Gently mix the tablet and liquid by stirring, taking care not to crush the tablet.
3. Stir until the tablet disperses into little pellets.
4. Drink the liquid with pellets immediately, or within 30min. DO not chew the pellets.
5. Rinse the glass with half a glass of water and drink.

When to take / use APO-Omeprazole

- APO-Omeprazole should be taken at the same time each day. Taking at the same day each time 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.

If you forget to use APO-Omeprazole

APO-Omeprazole should be used regularly at the same time each day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you use too much APO-Omeprazole

If you think that you have used too much APO-Omeprazole, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using APO-Omeprazole?

Things you should do

Call your doctor straight away if you:

- Are about to start any new medicine, remind your doctor and pharmacist that you are taking Omeprazole
- Tell all doctors, dentists and pharmacists who are treating you that you are taking Omeprazole.
- Tell your doctors if you become pregnant while you are taking Omeprazole

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

Things you should not do

- Do not stop using this medicine suddenly or change the dosage without checking with your doctor.
- Do not take Omeprazole 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how APO-Omeprazole affects you.

No information on driving or using machines is reported till now.

Drinking alcohol

Tell your doctor if you drink alcohol.

Effect of alcohol may not have an impact on APO-Omeprazole.

Looking after your medicine

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 windowsill or in the car. Heat and dampness can destroy some medicines.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

When to discard your medicine

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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • Constipation • Nausea/vomiting • Flatulence(wind) • Stomach pain • Diarrhoea • Headache • Skin rashy, itchy skin • Dizziness • Dry or sore mouth 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Muscle pain, joint pain or weakness • “pins and needles” (tingling or numbness) in the hands and feet • Changes in sleep patterns • Increased sweating • Hair loss • Tremor • Mood changes, confusion, depression • Increase in breast size (males) • Fever, vomiting and abdominal cramps accompanied by diarrhoea with or without blood or mucous • Increased bruising, or bleeding more easily • Disturbance in hearing • Blurred vision 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.</p>

Very Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • swelling of the face, lips, mouth, tongue or throat, which may cause difficulty 	<p>Call your doctor straight away, or go straight</p>

<p>in breathing</p> <ul style="list-style-type: none"> • shortness of breath or 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 	<p>to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

When taking APO-Omeprazole, inflammation in your kidney may occur. Signs and symptoms may include decreased volume of urine or blood in your urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness. You should report such signs to the treating physician.

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 reflux symptoms return

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What APO-Omeprazole contains

Active ingredient (main ingredient)	Omeprazole
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Ascorbyl palmitate• Microcrystalline cellulose• Crospovidone• Magnesium stearate• Povidone• Lactose monohydrate• Hypromellose phthalate• Triacetin• Purified talc• Iron oxide red• Iron oxide black
Potential allergens	N/A

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

Contains Sugars as Lactose.

Do not take this medicine if you are allergic to any of these ingredients.

What APO-Omeprazole looks like

APO-Omeprazole 20mg is a red brown, oblong, enteric coated tablets.

APO-Omeprazole is available in:

Blister packs and bottles of 30 tablets.

Not all pack types may be available.

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

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

Who distributes APO-Omeprazole

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

This leaflet was prepared in September 2023.