

APO-ESOMEPRAZOLE

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-ESOMEPRAZOLE?

APO-ESOMEPRAZOLE contains the active ingredient esomeprazole magnesium. APO-ESOMEPRAZOLE is used to treat Reflux Oesophagitis, Upper gastrointestinal symptoms associated with non-steroidal anti-inflammatory drugs (NSAIDs) therapy, Peptic Ulcers Associated with Helicobacter pylori Infection, Zollinger-Ellison Syndrome and prevention of rebleeding of gastric or duodenal ulcers.

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

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

Do not use if you have ever had an allergic reaction to APO-ESOMEPRAZOLE 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-ESOMEPRAZOLE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-ESOMEPRAZOLE 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-ESOMEPRAZOLE?

- APO-ESOMEPRAZOLE is available as tablets. The dose of APO-ESOMEPRAZOLE tablets is usually 20 mg or 40 mg a day depending on what condition you are being treated for and how severe it is.
- Follow all directions given to you by your doctor and pharmacist carefully.

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

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

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using APO-ESOMEPRAZOLE.• Tell your doctor if you become pregnant while you are taking APO-ESOMEPRAZOLE.• Tell your doctor if your symptoms return.
Things you should not do	<ul style="list-style-type: none">• Do not take APO-ESOMEPRAZOLE to treat any other complaints unless your doctor tells you to.• Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how APO-ESOMEPRAZOLE affects you.
Looking after your medicine	<ul style="list-style-type: none">• Keep APO-ESOMEPRAZOLE in the blister pack until it is time to take it.• Keep it in a cool, dry place where the temperature stays below 25°C.

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

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. These include headache, stomach pain, constipation, diarrhoea, wind, nausea, vomiting, itching, skin rash, dizziness, dry mouth, swelling of hands, ankles or feet. However, some serious side effects may need urgent medical attention. These include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, severe skin reaction which may include rash, itching, redness, blistering or peeling of the skin, signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite, blood in the urine and increased or decreased urine output.

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-ESOMEPRAZOLE

Active ingredient: *esomeprazole magnesium*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-ESOMEPRAZOLE. **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-ESOMEPRAZOLE.**

Where to find information in this leaflet:

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

1. Why am I using APO-ESOMEPRAZOLE?

APO-ESOMEPRAZOLE contains the active ingredient esomeprazole magnesium. APO-ESOMEPRAZOLE is a type of medicine called proton-pump inhibitor. 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.

Reflux Oesophagitis

APO-ESOMEPRAZOLE is taken to treat reflux oesophagitis. 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. APO-ESOMEPRAZOLE is also taken to help stop reflux oesophagitis coming back or relapsing.

Upper gastrointestinal symptoms associated with non-steroidal anti-inflammatory drugs (NSAIDs) therapy

APO-ESOMEPRAZOLE is taken to treat the symptoms of pain or discomfort in the stomach caused by NSAIDs, a type of medicine for pain or inflammation.

APO-ESOMEPRAZOLE is also taken to help heal and prevent ulcers caused by NSAIDs.

Peptic Ulcers Associated with *Helicobacter pylori* Infection

Most people who have a peptic (gastric and duodenal) ulcer also have a bacterium called *Helicobacter pylori* in their stomach.

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.

If you have a peptic ulcer, your doctor will prescribe APO-ESOMEPRAZOLE with antibiotics. When APO-ESOMEPRAZOLE and antibiotics are taken together, they work to kill the bacterium and let your ulcer heal. You may need further treatment with antibiotics.

Zollinger-Ellison syndrome

APO-ESOMEPRAZOLE 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.

Bleeding Peptic Ulcers

APO-ESOMEPRAZOLE is also used as prolonged treatment after prevention of rebleeding of ulcers of stomach or gut with intravenous esomeprazole.

When peptic ulcers become severe enough, they start to bleed. You may receive treatment injected into your veins initially. This treatment may be followed with APO-ESOMEPRAZOLE tablets prescribed by your doctor for a longer period of time. This is to help your ulcer/s to heal.

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

Warnings

Do not use this medicine if:

- you are allergic to esomeprazole magnesium, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- You are allergic to any medicines containing proton-pump inhibitors.

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 APO-ESOMEPRAZOLE if you are taking atazanavir or cilostazol. Please check with your doctor or pharmacist if you are taking these medicines. These medicines will be affected by APO-ESOMEPRAZOLE.

Check with your doctor if you:

- allergies to any other medicines, foods, dyes or preservatives
- any problems with your liver
- experienced any significant weight loss, difficulty in swallowing or dark tarry stools
- severe kidney problems
- any other medical conditions
- been diagnosed with osteoporosis

- ever had a skin reaction after treatment with a medicine similar to APO-ESOMEPRAZOLE that reduces stomach acid

There is no evidence that APO-ESOMEPRAZOLE is addictive.

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.

It is not known if it is safe for you to take APO-ESOMEPRAZOLE while you are pregnant. It may affect you baby.

It is not known if your baby can take APO-ESOMEPRAZOLE from breast milk if you are breastfeeding.

Do not take APO-ESOMEPRAZOLE if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

Children younger than 1 year:

APO-ESOMEPRAZOLE is not approved for use in children younger than 1 year of age. There is no specific information about use in children younger than 1 year of age, so APO-ESOMEPRAZOLE is not recommended in these patients.

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.

Do not take APO-ESOMEPRAZOLE if you are taking the following medicines:

- atazanavir and nelfinavir (used to treat viral infections such as HIV)
- cilostazol (used to reduce leg pain when walking caused by blood circulation disease)

Some medicines may interfere with APO-ESOMEPRAZOLE and affect how it works. These include:

- Ketoconazole, itraconazole and voriconazole – medicines used to treat fungal infection
- Diazepam – a medicine used to treat anxiety and some other conditions
- Phenytoin – a medicine used to treat epilepsy or fits
- Citalopram, clomipramine and imipramine – medicines used to treat depression
- St. John's wort – a herbal remedy used to treat mood disorders
- Clarithromycin and rifampicin – medicines used to treat bacterial infections

- Warfarin and clopidogrel – medicines used to prevent blood clots
- Digoxin – a medicine used to treat heart conditions
- Methotrexate – a medicine used to treat arthritis and some types of cancer
- Tacrolimus and mycophenolate mofetil – medicines used to assist in organ transplants
- erlotinib or related medicines used to treat cancer
- cisapride

These medicines may be affected by APO-ESOMEPRAZOLE 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.

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-ESOMEPRAZOLE.

4. How do I use APO-ESOMEPRAZOLE?

How much to take

- Take one APO-ESOMEPRAZOLE tablet each day, unless your doctor has told you otherwise.
- The dose of APO-ESOMEPRAZOLE tablets is usually 20 mg or 40 mg a day depending on what condition you are being treated for and how severe it is.

When to take APO-ESOMEPRAZOLE

- Take APO-ESOMEPRAZOLE at about the same time each day.
- Keeping a regular time for taking APO-ESOMEPRAZOLE will help to remind you to take it.
- APO-ESOMEPRAZOLE can be taken with food or on an empty stomach.
- Keep taking APO-ESOMEPRAZOLE for as long as your doctor recommends.
- In most patients, APO-ESOMEPRAZOLE relieves symptoms rapidly and healing is usually complete within 4 weeks. Continue taking APO-ESOMEPRAZOLE for as long as your doctor tells you to.

How to take APO-ESOMEPRAZOLE

Swallow APO-ESOMEPRAZOLE 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.

If you have difficulty swallowing the tablets:

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

If you cannot swallow at all, follow steps 1-3 above to disperse the tablets and administer the liquid and pellets through a gastric tube.

If you forget to use APO-ESOMEPRAZOLE

APO-ESOMEPRAZOLE should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking it as you would normally.

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 have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you use too much APO-ESOMEPRAZOLE

If you think that you have used too much APO-ESOMEPRAZOLE, 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-ESOMEPRAZOLE?

Things you should do

Take APO-ESOMEPRAZOLE exactly as your doctor has prescribed.

If you are about to start on any new medicine, tell your doctor, dentist or pharmacist that you are taking APO-ESOMEPRAZOLE.

Tell all doctors, dentists and pharmacists who are treating you that you are taking APO-ESOMEPRAZOLE.

Tell your doctor if you become pregnant while you are taking APO-ESOMEPRAZOLE.

Tell your doctor if your symptoms return.

Although APO-ESOMEPRAZOLE 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 APO-ESOMEPRAZOLE, tell your doctor.

It may affect the results of some tests.

Things you should not do

- Do not take it to treat any other complaints unless your doctor tells you to.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Driving or using machines

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

Looking after your medicine

- Keep your APO-ESOMEPRAZOLE in the blister pack until it is time to take them. If you take APO-ESOMEPRAZOLE out of the blister pack it will not keep well.
- Keep it in a cool, dry place where the temperature stays below 25°C.

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

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

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.

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">• Nausea or vomiting• Constipation• diarrhoea• headache• wind• stomach pain• skin rash, itchy skin• dizziness• dry mouth• swelling of hands, ankles or feet	Speak to your doctor if you have any of these less serious side effects and they worry you.
<ul style="list-style-type: none">• blurred vision• mood changes, confusion or depression• muscle pain or weakness• joint pain• increase in breast size (males)• increased sweating• changes in sleep patterns	Speak to your doctor immediately if you notice any of these side effects.

<ul style="list-style-type: none"> • fever • increased bruising • “pins and needles” • hair loss • tremor • blood in urine • skin reaction, especially in sun-exposed areas, with joint pain • muscle twitching or jerking movements • irregular (fast or slow) heartbeat • loss of consciousness or awareness 	<p>These side effects may require medical attention</p>
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • shortness of breath, wheezing or difficulty breathing • swelling of the face, lips, tongue or other parts of the body • severe skin reaction which may include rash, itching, redness, blistering or peeling of the skin. This may be associated with a high fever and joint pains. • Signs of liver inflammation (often seen as yellowing of your skin, feeling generally unwell, nausea, vomiting, loss of appetite) • blood in the urine • increased or decreased urine output 	<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>
<ul style="list-style-type: none"> • pain or indigestion during treatment with APO-ESOMEPRAZOLE • you begin to vomit blood or food • you pass black (blood-stained) motions <p>Tell your doctor if your reflux symptoms return after you stop taking APO-ESOMEPRAZOLE.</p>	<p>Contact your doctor immediately if you notice any of these side effects.</p>

Occasionally, APO-ESOMEPRAZOLE 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 else that may be making you feel unwell.

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

Other problems are more likely to arise from the condition itself rather than the treatment.

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-ESOMEPRAZOLE contains

Active ingredient (main ingredient)	esomeprazole magnesium
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • Non Pareil Seeds 40-60 [sugar spheres (sucrose and maize starch)] • Proprietary ingredient # 108075] • Hyprolose • crospovidone, • povidone, • macrogol 400, • purified talc • hypromellose phthalate, diethyl phthalate • macrogol 6000, • microcrystalline cellulose • sodium stearyl-fumarate • macrogol 4000 • Opadry Complete Film Coating System 03B86651 • Brown (Proprietary Ingredient # 106495)
Potential allergens	sugars

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

What APO-ESOMEPRAZOLE looks like

APO-ESOMEPRAZOLE 20 mg tablets are light brick red to brown, oval, biconvex, enteric-coated tablets with ‘E5’ debossed on one side and plain on other side. (AUST R 184774)

APO-ESOMEPRAZOLE 40 mg tablets are light brick red to brown, oval, biconvex, enteric-coated tablets with ‘E6’ debossed on one side and plain on other side. (AUST R 184761)

Who distributes APO-ESOMEPRAZOLE

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121
www.arrotex.com.au

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