

APO-ESOMEPRAZOLE Tablets

Esomeprazole magnesium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about APO-ESOMEPRAZOLE. 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 APO-ESOMEPRAZOLE against the benefits it is expected to 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 APO-ESOMEPRAZOLE is used for

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.

Prevention of rebleeding of gastric or duodenal 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 for a longer period of time. This is to help your ulcer/s to heal.

How APO-ESOMEPRAZOLE works

APO-ESOMEPRAZOLE is a type of medicine called a 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.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Ask your doctor if you want more information.

Your doctor may have prescribed APO-ESOMEPRAZOLE for another reason. There is no evidence that APO-ESOMEPRAZOLE is addictive.

Before you take APO-ESOMEPRAZOLE

When you must not take APO-ESOMEPRAZOLE

Do not take APO-ESOMEPRAZOLE if you have allergies to:

- Esomeprazole or any ingredient listed at the end of this leaflet
- Any medicines 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 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.

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.

Do not take APO-ESOMEPRAZOLE after the use by (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.

Before you start to take it

You must tell your doctor if you have:

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

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

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

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

Taking other medicines

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

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

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

Some medicines may interfere with APO-ESOMEPRAZOLE. These include:

- medicines used to treat fungal infections such as ketoconazole, itraconazole and voriconazole
- medicines used to treat bacterial infections such as clarithromycin and rifampicin
- cisapride
- diazepam, a medicine used to treat anxiety and some other conditions
- phenytoin, a medicine used to treat epilepsy

- medicines used to treat depression such as citalopram, clomipramine or imipramine
- warfarin and clopidogrel - medicines used to prevent blood clots
- digoxin, a medicine used to treat certain heart problems
- medicines for HIV treatment such as nelfinavir
- St. John's Wort, a herbal remedy used to treat mood disorders
- methotrexate, a medicine used to treat arthritis and some types of cancer
- tacrolimus and mycophenolate mofetil – a medicine used to assist in organ transplants
- erlotinib or related medicines used to treat cancer

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.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking APO-ESOMEPRAZOLE.

If you have not told your doctor about any of these things, tell them before you take APO-ESOMEPRAZOLE.

How to take APO-ESOMEPRAZOLE

Follow all directions given to you by your doctor and pharmacist carefully.

These instructions may differ from the information contained in this leaflet.

If you do not understand the directions on the label, ask your doctor or pharmacist for help.

How to take it

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.

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.

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.

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.

APO-ESOMEPRAZOLE can be taken with food or on an empty stomach.

If you forget to take it

If you forget to take a dose, 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 that you missed.

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

Taking too much (overdose)

Telephone your doctor or the Poisons Information Centre (13 11 26) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too many APO-ESOMEPRAZOLE tablets. Do this even if there are no signs of discomfort or poisoning.

While you are taking APO-ESOMEPRAZOLE

Things you must do

Take APO-ESOMEPRAZOLE exactly as your doctor has prescribed.

If you are about to be started 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 must 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.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking APO-ESOMEPRAZOLE.

APO-ESOMEPRAZOLE helps most people with peptic ulcers or reflux disease, 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 treatment if you get some of the side effects.

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:

- headache
- stomach pain
- constipation
- diarrhoea
- wind
- nausea
- vomiting
- itching
- skin rash

- dizziness
- dry mouth
- swelling of hands, ankles or feet

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- blurred vision
- mood changes, confusion or depression
- increase in breast size (males)
- increased sweating
- changes in sleep patterns
- 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

These side effects may require medical attention.

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

- 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.
- liver problems (often seen as yellowing of your skin or the whites of your eyes, feeling generally unwell, nausea, vomiting, loss of appetite)

These are very serious side effects. You may need urgent medical treatment or hospitalisation. These side effects are rare.

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 if you think you have any of these effects or notice anything else that is making you feel unwell.

Some people may get other side effects while taking APO-ESOMEPRAZOLE. Other problems are more likely to arise from the condition itself rather than the treatment.

For this reason, contact your doctor immediately if you notice any of the following:

- pain or indigestion during treatment with APO-ESOMEPRAZOLE
- you begin to vomit blood or food
- you pass black (blood-stained) motions

Tell your doctor if your reflux symptoms return after you stop taking APO-ESOMEPRAZOLE.

After taking APO-ESOMEPRAZOLE

Storage

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.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on a window sill. Heat and dampness can destroy some medicines.

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.

Disposal

If your doctor tells you to stop taking APO-ESOMEPRAZOLE or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets you have left over.

Product description

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.

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.

Ingredients

Active ingredient:

APO-ESOMEPRAZOLE 20 mg tablets – esomeprazole magnesium equivalent to 20 mg esomeprazole

APO-ESOMEPRAZOLE 40 mg tablets – esomeprazole magnesium equivalent to 40 mg esomeprazole

Inactive ingredients:

Non Pareil Seeds 40-60 [sugar spheres (sucrose and maize starch); Proprietary ingredient # 108075], hypolose, crospovidone, povidone, macrogol 400, purified talc, hypromellose phthalate, diethyl phthalate, macrogol 6000, microcrystalline cellulose, sodium stearyl fumarate, macrogol 4000 and Opadry Complete Film Coating System 03B86651 Brown (Proprietary Ingredient # 106495). APO-ESOMEPRAZOLE tablets contains sugars. APO-ESOMEPRAZOLE tablets do not contain lactose, glucose or gluten.

Sponsor

Arrotex Pharmaceuticals Pty Ltd
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www.arrotex.com.au

*Australian Registration
Numbers*

APO-ESOMEPRAZOLE 20 mg
tablets: AUST R 184774
APO-ESOMEPRAZOLE 40 mg
tablets: AUST R 184761

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