

# ESOPREZE

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## 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.

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### 1. Why am I taking ESOPREZE?

ESOPREZE contains the active ingredient esomeprazole magnesium trihydrate. ESOPREZE is used to treat reflux conditions and ulcers. ESOPREZE is also taken to help stop reflux coming back or relapsing. For more information, see Section [1. Why am I taking ESOPREZE?](#) in the full CMI.

### 2. What should I know before I take ESOPREZE?

Do not take ESOPREZE if you have ever had an allergic reaction to esomeprazole or any of the ingredients listed at the end of the CMI. Do not use if you have allergies to any medicines containing a proton pump inhibitor.

**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 take ESOPREZE?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with ESOPREZE 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 take ESOPREZE?

- Take one ESOPREZE tablet each day, unless your doctor has told you otherwise.
- Swallow ESOPREZE 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.

More instructions can be found in Section [4. How do I take ESOPREZE?](#) in the full CMI.

### 5. What should I know while taking ESOPREZE?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist, or pharmacist you visit that you are taking ESOPREZE.</li><li>• Tell your doctor or pharmacist as soon as possible if you do not</li></ul>
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	feel well while you are taking ESOPREZE.
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not take it to treat any other complaints unless your doctor tells you to.</li> <li>• Do not give this medicine to anyone else, even if their symptoms seem similar to yours.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• ESOPREZE is unlikely to affect your ability to drive or to operate machinery.</li> </ul>
<b>Food and Drink</b>	<ul style="list-style-type: none"> <li>• ESOPREZE can be taken with food or on an empty stomach.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep it in a cool, dry place where the temperature stays below 25°C.</li> <li>• Keep your ESOPREZE tablets in the blister pack until it is time to take it.</li> </ul>

For more information, see Section [5. What should I know while taking ESOPREZE?](#) in the full CMI.

## 6. Are there any side effects?

All medicines can have side effects. If they do occur, they are usually minor and temporary. Do not be alarmed by this list.

You may not experience any of them. The most common side effects are stomach complaints and headache. The more serious and uncommon or rare side effects are blurred vision, mood changes, confusion or depression, muscle pain or weakness, joint pain, increase in breast size (males), increased sweating, changes in sleep patterns, fever, increased bruising, "pins and needles", hair loss, tremor, blood in the urine, skin reaction, especially in sun-exposed areas, with joint pain, swelling of body parts, difficulty breathing, skin reactions or signs of liver inflammation.

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.

# ESOPREZE

**Active ingredient:** esomeprazole magnesium trihydrate

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## Consumer Medicine Information (CMI)

This leaflet provides important information about taking ESOPREZE. **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 ESOPREZE.**

**Where to find information in this leaflet:**

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

## 1. Why am I taking ESOPREZE?

**ESOPREZE contains the active ingredient esomeprazole magnesium trihydrate.** ESOPREZE 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.

**ESOPREZE is used to treat reflux oesophagitis.**

This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe (oesophagus). ESOPREZE is also taken to help stop reflux oesophagitis coming back or relapsing.

**ESOPREZE is taken to treat the symptoms of pain or discomfort in the stomach caused by NSAIDs, a type of medicine for pain or inflammation.** ESOPREZE is also taken to help heal and prevent ulcers caused by NSAIDs.

**ESOPREZE together with antibiotics is taken to treat peptic ulcer.** Most people who have a peptic (gastric and duodenal) ulcer also have a bacterium called *Helicobacter pylori* in their stomach.

When ESOPREZE and antibiotics are taken together, they work to kill the bacterium and let your ulcer heal. You may need further treatment with antibiotics.

**ESOPREZE is also used to treat a rare condition called Zollinger-Ellison syndrome.** This is a condition where the stomach produces large amounts of acid, much more than in ulcers or reflux disease.

**ESOPREZE is taken as follow up treatment for bleeding peptic ulcers.**

## 2. What should I know before I take ESOPREZE?

### Warnings

#### Do not use ESOPREZE if:

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

ESOPREZE is not approved for use in children younger than 1 year of age.

#### Check with your doctor if you:

- have any allergies to any other medicines or foods
- have any other medical conditions such as any problems with your liver, severe kidney problems
- have been diagnosed with osteoporosis
- have ever had a skin reaction after treatment with a medicine similar to ESOPREZE that reduces stomach acid
- take any medicines for any other 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.

**Do not take ESOPREZE if you are pregnant or breastfeeding unless your doctor says so.**

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

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

## **3. What if I am taking other medicines?**

**Do not take ESOPREZE if you are taking the following medicines:**

- atazanavir and nelfinavir - medicines used to treat viral infections such as human immunodeficiency virus (HIV)
- cilostazol - a medicine used to treat intermittent claudication



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 ESOPREZE and affect how it works.**

These include:

- ketoconazole, itraconazole and voriconazole - medicines used to treat fungal infections
- 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

These medicines may be affected by ESOPREZE 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 ESOPREZE.**

## **4. How do I take ESOPREZE?**

### **How much to take**

- Take one ESOPREZE tablet each day, unless your doctor has told you otherwise. The dose of ESOPREZE 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 the instructions provided and use ESOPREZE until your doctor tells you to stop.

### **When to take ESOPREZE**

- Take ESOPREZE at about the same time each day.
- Keeping a regular time for taking ESOPREZE will help to remind you to take it.

### **How to take ESOPREZE**

Swallow ESOPREZE 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 take ESOPREZE**

ESOPREZE should be taken 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 take too much ESOPREZE**

If you think that you have taken too much ESOPREZE, 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 taking ESOPREZE?**

### **Things you should do**

**Take ESOPREZE 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 ESOPREZE.**

**Tell all doctors, dentists and pharmacists who are treating you that you are taking ESOPREZE.**

**Tell your doctor if you become pregnant while you are taking ESOPREZE.**

**Tell your doctor if your symptoms return.**

**If you need to have any medical tests while you are taking ESOPREZE, tell your doctor.**

Remind any doctor, dentist, or pharmacist you visit that you are using ESOPREZE.

## **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 ESOPREZE affects you.**

ESOPREZE is unlikely to affect your ability to drive or to operate machinery.

## **Food and drink**

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

## **Looking after your medicine**

- Keep your ESOPREZE tablets in the blister pack until it is time to take it.

Store ESOPREZE 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 ESOPREZE where young children cannot reach it.**

## Getting rid of any unwanted medicine

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

Do not take 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"><li>• nausea or vomiting</li><li>• constipation</li><li>• diarrhoea</li><li>• headache</li><li>• wind</li><li>• stomach pain</li><li>• skin rash, itchy skin</li><li>• dizziness</li><li>• dry mouth</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
These side effects are usually mild.	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● blurred vision</li> <li>● mood changes, confusion, or depression</li> <li>● muscle pain or weakness, joint pain</li> <li>● increase in breast size (males)</li> <li>● increased sweating</li> <li>● changes in sleep patterns</li> <li>● fever</li> <li>● increased bruising</li> <li>● "pins and needles"</li> <li>● hair loss</li> <li>● tremor</li> <li>● blood in the urine</li> <li>● skin reaction, especially in sun-exposed areas, with joint pain</li> </ul>	<p><b>Call your doctor straight away if you notice any of these side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● muscle twitching or jerking movements</li> <li>● irregular (fast or slow) heartbeat</li> <li>● loss of consciousness or awareness</li> </ul> <p>These side effects may require medical attention.</p>	
<ul style="list-style-type: none"> <li>● shortness of breath, wheezing or difficulty breathing</li> <li>● swelling of the face, lips, tongue, or other parts of the body</li> <li>● severe skin reaction which may include rash, itching, redness, blistering or peeling of the skin</li> <li>● signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite</li> </ul> <p>These are very serious side effects. You may need urgent</p>	<p><b>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.</b></p>



<b>Serious side effects</b>	<b>What to do</b>
medical treatment or hospitalisation.	

Occasionally, ESOPREZE 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.

Some 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 ESOPREZE
- 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 ESOPREZE.

## **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](http://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 ESOPREZE.**

## **7. Product details**

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

### **What ESOPREZE contains**

<b>Active ingredient (main ingredient)</b>	esomeprazole magnesium trihydrate
<b>Other ingredients (inactive ingredients)</b>	glyceryl monostearate hyprolose hypromellose magnesium stearate methacrylic acid copolymer microcrystalline cellulose synthetic paraffin macrogol 6000 polysorbate 80 crospovidone sodium stearyl fumarate

	<p>purified talc</p> <p>titanium dioxide</p> <p>triethyl citrate</p> <p>sugar spheres (maize starch and sucrose)</p> <p>The tablets are coloured with iron oxide red and/or iron oxide yellow.</p>
<b>Potential allergens</b>	sorbates

**Do not take ESOPREZE if you are allergic to any of these ingredients.**

## **What ESOPREZE looks like**

ESOPREZE 20 mg are light pink, oblong shaped tablets engraved 20 mg on one side and A / EH on the other (AUST R 349670).

ESOPREZE 40 mg are pink, oblong shaped tablets engraved 40 mg on one side and A / EI on the other (AUST R 349671).

## **Who distributes ESOPREZE?**

AstraZeneca Pty Ltd  
 ABN 54 009 682 311  
 66 Talavera Road  
 Macquarie Park NSW 2113

Telephone: 1800 805 342

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