

MEPREZE® 24HR ONCE DAILY DOSING

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 MEPREZE® 24HR Once daily dosing?

MEPREZE® 24HR Once daily dosing contains the active ingredient esomeprazole magnesium dihydrate. MEPREZE® 24HR Once daily dosing is used for the symptomatic relief of heartburn and other symptoms associated with gastroesophageal reflux disease (GORD).

For more information, see Section [1. Why am I using MEPREZE® 24HR Once daily dosing?](#) in the full CMI.

2. What should I know before I use MEPREZE® 24HR Once daily dosing?

Do not use if you have ever had an allergic reaction to MEPREZE® 24HR Once daily dosing or any of the ingredients listed at the end of the CMI or if you are also taking atazanavir or cilostazol.

Talk to your doctor or pharmacist 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 MEPREZE® 24HR Once daily dosing?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MEPREZE® 24HR Once daily dosing 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 MEPREZE® 24HR Once daily dosing?

- Take one MEPREZE® 24HR Once daily dosing tablet each day.
- Swallow MEPREZE® 24HR Once daily dosing tablets whole with a glass of water. Do not crush or chew the tablets.

More instructions can be found in Section [4. How do I use MEPREZE® 24HR Once daily dosing?](#) In the full CMI.

5. What should I know while using MEPREZE® 24HR Once daily dosing?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, or pharmacist you visit that you are taking MEPREZE® 24HR Once daily dosing.• Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking MEPREZE® 24HR Once daily dosing.
Things you should not do	<ul style="list-style-type: none">• 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	MEPREZE® 24HR Once daily dosing is unlikely to affect your ability to drive or to operate machinery.
Looking after your medicine	<ul style="list-style-type: none">• Keep it in a cool, dry place where the temperature stays below 25°C.• Keep your MEPREZE® 24HR Once daily dosing tablets in the blister pack until it is time to take it.

For more information, see Section [5. What should I know while using MEPREZE® 24HR Once daily dosing?](#) 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.

MEPREZE® 24HR ONCE DAILY DOSING

Active ingredient: esomeprazole magnesium dihydrate

Consumer Medicine Information (CMI)

This leaflet provides important information about using MEPREZE® 24HR Once daily dosing. **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 MEPREZE® 24HR Once daily dosing.**

Where to find information in this leaflet:

- [1. Why am I using MEPREZE® 24HR Once daily dosing?](#)
- [2. What should I know before I use MEPREZE® 24HR Once daily dosing ?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use MEPREZE® 24HR Once daily dosing?](#)
- [5. What should I know while using MEPREZE® 24HR Once daily dosing?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using MEPREZE® 24HR Once daily dosing?

MEPREZE® 24HR Once daily dosing contains the active ingredient esomeprazole magnesium dihydrate.

MEPREZE® 24HR Once daily dosing is taken for the symptomatic relief of heartburn and other symptoms associated with gastro-oesophageal reflux disease (GORD). 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.

Esomeprazole belongs to a group of medicines called proton-pump inhibitors.

This medicine 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 esomeprazole is addictive.

2. What should I know before I use MEPREZE® 24HR Once daily dosing?

Warnings

Do not use MEPREZE® 24HR Once daily dosing if:

- You are allergic to esomeprazole, 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 a proton pump inhibitor.
- You are taking atazanavir (a medicine used in HIV).
- You are taking cilostazol (a medicine used for intermittent claudication).

Check with your doctor or pharmacist if you:

- have any allergies to any other medicines or foods, dyes or preservatives
- have ever had a skin reaction after treatment with a medicine similar to MEPREZE® 24HR Once daily dosing that reduces stomach acid
- have any other medical conditions such as any problems with your liver, severe kidney problems, anaemia, previous gastric ulcer or gastrointestinal surgery, difficulty swallowing, persistent vomiting or vomiting of blood, blood in stools, unexplained weight loss or osteoporosis
- 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 or pharmacist if you are pregnant or intend to become pregnant.

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

Do not take MEPREZE® 24HR Once daily dosing if you are pregnant or breastfeeding unless your doctor or pharmacist says so.

Your doctor can discuss with you the risks and benefits involved.

Use in children and adolescents

This medicine is not approved for use in children and adolescents younger than 18 years of age.

3. What if I am taking other medicines?

Do not take MEPREZE® 24HR Once daily dosing 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 pain and/or cramping of the lower leg (or arms) due to inadequate blood flow to the muscles

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 MEPREZE® 24HR Once daily dosing 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 MEPREZE® 24HR or may affect how well it works. You may need different amounts of your medicine or you may need to take different 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 MEPREZE® 24HR Once daily dosing.

4. How do I use MEPREZE® 24HR Once daily dosing?

How much to take

- Take one MEPREZE® 24HR Once daily dosing tablet each day.

When to take MEPREZE® 24HR Once daily dosing

- Take MEPREZE® 24HR Once daily dosing at about the same time each day.
- Taking it at the same time each day will have the best effect. It will also help you remember when to take it. This medicine can be taken with food or on an empty stomach.

How to take MEPREZE® 24HR Once daily dosing

Swallow MEPREZE® 24HR Once daily dosing 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.

How long to take it

This medicine should be taken for at least 7 days and up to 14 days.

If you purchased a pack containing 7 days supply and you need to take longer than 7 days, ask your pharmacist for advice.

Do not take beyond 14 days without consulting your doctor.

If you forget to take MEPREZE® 24HR Once daily dosing

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 use too much MEPREZE® 24HR Once daily dosing

If you think that you have used too much MEPREZE® 24HR Once daily dosing, 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 MEPREZE® 24HR Once daily dosing?

Things you should do

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking MEPREZE® 24HR Once daily dosing.

Tell all doctors, dentists and pharmacists who are treating you that you are taking MEPREZE® 24HR Once daily dosing.

Tell your doctor or pharmacist if you become pregnant while you are taking MEPREZE® 24HR Once daily dosing.

Tell your pharmacist or doctor if you do not feel better while taking MEPREZE® 24HR Once Daily dosing. If symptoms persist or recur within 2 weeks of completing the course, consult a doctor. Further examination may be required.

If you need to have any medical tests while you are taking MEPREZE® 24HR Once daily dosing, tell your pharmacist or doctor.

It may affect the results of some tests.

Things you should not do

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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how MEPREZE® 24HR Once daily dosing affects you.

MEPREZE® 24HR Once daily dosing is unlikely to affect your ability to drive or to operate machinery.

Drinking alcohol

Tell your doctor or pharmacist if you drink alcohol.

Looking after your medicine

Keep your MEPREZE® 24HR Once daily dosing tablets in the blister pack until it is time to take it.

Store MEPREZE® 24HR Once daily dosing below 25°C 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 MEPREZE® 24HR Once daily dosing where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to take MEPREZE® 24HR Once daily dosing 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.

Common side effects

Common 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 	<p>Speak to your doctor or pharmacist if you have any of these common side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<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 • fever • increased bruising • "pins and needles" • hair loss • tremor • blood in the urine • 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 	<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>

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.

Occasionally, esomeprazole may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

Withdrawal of long-term PPI therapy may lead to worsening of acid related symptoms.

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 MEPREZE® 24HR Once daily dosing
- you begin to vomit blood or food
- you pass black (blood-stained) motions

Tell your doctor or pharmacist if your reflux symptoms return after you stop taking MEPREZE® 24HR Once daily dosing.

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.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What MEPREZE® 24HR Once daily dosing contains

Active ingredient (main ingredient)	esomeprazole magnesium dihydrate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• methacrylic acid polymer• purified talc• triethyl citrate• hypromellose• hyprolose• sucrose• maize starch• magnesium stearate• hydroxypropyl cellulose• glyceryl monostearate• polysorbate 80• microcrystalline cellulose• povidone• macrogol 6000• crospovidone• sodium stearyl fumarate• titanium dioxide• macrogol 400• iron oxide red• iron oxide yellow

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

What MEPREZE® 24HR Once daily dosing looks like

MEPREZE® 24HR Once daily dosing 20 mg tablet: light pink, elliptically shaped, biconvex, enteric coated tablet. (Aust R 300206)

Who distributes MEPREZE® 24HR Once daily dosing

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia

Tel 1800 726 369

This leaflet was prepared in November 2023.

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