

ESOMEPRAZOLE VIATRIS

Consumer Medicine Information (CMI) summary

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

1. Why am I taking ESOMEPRAZOLE VIATRIS?

ESOMEPRAZOLE VIATRIS contains the active ingredient esomeprazole (as magnesium dihydrate). ESOMEPRAZOLE VIATRIS 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 bleeding peptic ulcers.

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

2. What should I know before I take ESOMEPRAZOLE VIATRIS?

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

3. What if I am taking other medicines?

Some medicines may interfere with ESOMEPRAZOLE VIATRIS 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 ESOMEPRAZOLE VIATRIS?

- The dose of ESOMEPRAZOLE VIATRIS tablets is usually 20 mg or 40 mg a day. The dose you are prescribed will depend on the 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 take ESOMEPRAZOLE VIATRIS?](#) in the full CMI.

5. What should I know while taking ESOMEPRAZOLE VIATRIS?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using ESOMEPRAZOLE VIATRIS. • Tell your doctor if you become pregnant while you are taking ESOMEPRAZOLE VIATRIS. • Tell your doctor if your symptoms return.
Things you should not do	• Do not take ESOMEPRAZOLE VIATRIS 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 ESOMEPRAZOLE VIATRIS affects you.
Looking after your medicine	• Keep your ESOMEPRAZOLE VIATRIS in the blister pack until it is time to take it. • Store in a cool, dry place where the temperature stays below 25°C.

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

6. Are there any side effects?

Some of the less serious side effects include nausea or vomiting, constipation, diarrhoea, headache, wind, stomach pain, skin rash, itchy skin, dizziness or dry mouth. Some of the more serious side effects 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. This is not an exhaustive list of 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.

ESOMEPRAZOLE VIATRIS

Active ingredient: *esomeprazole (as magnesium dihydrate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking ESOMEPRAZOLE VIATRIS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking ESOMEPRAZOLE VIATRIS.**

Where to find information in this leaflet:

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

1. Why am I taking ESOMEPRAZOLE VIATRIS?

ESOMEPRAZOLE VIATRIS contains the active ingredient esomeprazole (as magnesium dihydrate). ESOMEPRAZOLE VIATRIS 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.

Reflux Oesophagitis

ESOMEPRAZOLE VIATRIS 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. ESOMEPRAZOLE VIATRIS is also taken to help stop reflux oesophagitis coming back or relapsing.

Upper Gastrointestinal Symptoms Associated with Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) Therapy

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

ESOMEPRAZOLE VIATRIS 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 ESOMEPRAZOLE VIATRIS with antibiotics. When ESOMEPRAZOLE VIATRIS 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

ESOMEPRAZOLE VIATRIS 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

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 ESOMEPRAZOLE VIATRIS prescribed by your doctor for a longer period of time. This is to help your ulcer/s to heal.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

Your doctor may have prescribed ESOMEPRAZOLE VIATRIS for another reason.

2. What should I know before I take ESOMEPRAZOLE VIATRIS?

Warnings

Do not take ESOMEPRAZOLE VIATRIS 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.
Some of the symptoms of an allergic reaction may include:
 - o shortness of breath
 - o wheezing or difficulty breathing
 - o swelling of the face, lips, tongue or other parts of the body
 - o rash, itching or hives on the skin

Always check the ingredients to make sure you can take this medicine.

Do not take ESOMEPRAZOLE VIATRIS if you are also taking atazanavir or cilostazol. Please check with your doctor or pharmacist if you are taking these medicines. These medicines will be affected by ESOMEPRAZOLE VIATRIS.

Do not take ESOMEPRAZOLE VIATRIS 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.

Check with your doctor if you have:

- allergies to any other medicines, foods, dyes or preservatives
- any problems with your liver
- severe kidney problems
- any other medical conditions
- been diagnosed with osteoporosis
- ever had a skin reaction after treatment with a
- medicine similar to ESOMEPRAZOLE VIATRIS that reduces stomach acid

There is no evidence that ESOMEPRAZOLE VIATRIS 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.

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

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

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

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

Children under 1 year:

ESOMEPRAZOLE VIATRIS 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 ESOMEPRAZOLE VIATRIS is not recommended in these patients.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking, or have recently been 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 ESOMEPRAZOLE VIATRIS 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

Some medicines that may interfere with ESOMEPRAZOLE VIATRIS 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 ESOMEPRAZOLE VIATRIS or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

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

4. How do I take ESOMEPRAZOLE VIATRIS?

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information provided in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

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

Children 1-11 years

Alternative preparations (oral suspensions) will be required for children in this age range.

When to take ESOMEPRAZOLE VIATRIS

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

How to take ESOMEPRAZOLE VIATRIS

Swallow ESOMEPRAZOLE VIATRIS 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 ESOMEPRAZOLE VIATRIS

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

If you take too much ESOMEPRAZOLE VIATRIS

If you think that you or anyone else has taken too much ESOMEPRAZOLE VIATRIS, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 ESOMEPRAZOLE VIATRIS?

Things you should do

- Take ESOMEPRAZOLE VIATRIS 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 ESOMEPRAZOLE VIATRIS.
- Tell all doctors, dentists and pharmacists who are treating you that you are taking ESOMEPRAZOLE VIATRIS.
- Tell your doctor if you become pregnant while you are taking ESOMEPRAZOLE VIATRIS.

- Tell your doctor if your symptoms return.

Although ESOMEPRAZOLE VIATRIS 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 ESOMEPRAZOLE VIATRIS, 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 ESOMEPRAZOLE VIATRIS 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 ESOMEPRAZOLE VIATRIS affects you.

Looking after your medicine

- Keep your ESOMEPRAZOLE VIATRIS in the blister pack until it is time to take it. If you take ESOMEPRAZOLE VIATRIS out of the blister pack it will not keep well.
- Store 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 ESOMEPRAZOLE VIATRIS 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 take this medicine 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
• nausea or vomiting • constipation • diarrhoea • headache • wind • stomach pain	Speak to your doctor if you have any of these less serious side effects and

Less serious side effects	What to do
• skin rash, itchy skin • dizziness • dry mouth	they worry you. These side effects are usually mild.
• 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 • 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	Speak to your doctor immediately if you have any of these side effects. These side effects may require medical attention.

Serious side effects

Serious side effects	What to do
• 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 urine • increased or decreased urine output	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.
• pain or indigestion during treatment with ESOMEPRAZOLE VIATRIS • you begin to vomit blood or food • you pass black (blood-stained) motions	Contact your doctor immediately if you notice any of these side effects.

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

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

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.

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 ESOMEPRAZOLE VIATRIS contains

Active ingredient (main ingredient)	esomeprazole (as magnesium dihydrate) 20 mg or 40 mg
Other ingredients (inactive ingredients)	• methacrylic acid polymer • purified talc • triethyl citrate • hypromellose • 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 ESOMEPRAZOLE VIATRIS looks like

ESOMEPRAZOLE VIATRIS 20 mg tablets are elliptically shaped, biconvex, light pink enteric coated tablet (AUST R 210854).

ESOMEPRAZOLE VIATRIS 40 mg tablets are elliptically shaped, biconvex, pink, enteric-coated tablet (AUST R 210844).

ESOMEPRAZOLE VIATRIS tablets are available in blister packs of 30 tablets.

Who distributes ESOMEPRAZOLE VIATRIS

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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