

Esomeprazole GH

Consumer Medicine Information (CMI) Summary [optional]

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 Esomeprazole GH?

Esomeprazole GH contains the active ingredient esomeprazole magnesium trihydrate. Esomeprazole GH 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 using Esomeprazole GH?](#) in the full CMI.

2. What should I know before I use Esomeprazole GH?

Do not use if you have ever had an allergic reaction to Esomeprazole GH or any of the ingredients listed at the end of the CMI.

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 Esomeprazole GH?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Esomeprazole GH 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 Esomeprazole GH?

- Esomeprazole GH is available as either tablets or as granules for suspension in sachets. The dose of Esomeprazole GH tablets is usually 20 mg or 40 mg a day. The dose of Esomeprazole GH sachets is 10 mg to 20 mg a day. The dose for tablets or sachets depends 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 Esomeprazole GH?](#) in the full CMI.

5. What should I know while using Esomeprazole GH?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Esomeprazole GH.• Tell your doctor if you become pregnant while you are taking Esomeprazole GH.• Tell your doctor if your symptoms return.
Things you should not do	<ul style="list-style-type: none">• Do not take Esomeprazole GH 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 Esomeprazole GH affects you.
Looking after your medicine	<ul style="list-style-type: none">• Keep your Esomeprazole GH in the blister pack or sachet 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 Esomeprazole GH?](#) 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 nausea or vomiting, constipation, diarrhoea, headache, wind, stomach pain, skin rash, itchy skin, dizziness or dry mouth. 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.

Esomeprazole GH

Active ingredient(s): esomeprazole magnesium trihydrate

Consumer Medicine Information (CMI)

This leaflet provides important information about using Esomeprazole GH. **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 Esomeprazole GH.**

Where to find information in this leaflet:

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

1. Why am I using Esomeprazole GH?

Esomeprazole GH contains the active ingredient esomeprazole magnesium trihydrate. Esomeprazole GH 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 GH 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). Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn. Esomeprazole GH is also taken to help stop reflux oesophagitis coming back or relapsing.

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

Esomeprazole GH 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 GH 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 GH with antibiotics. When Esomeprazole GH 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 GH 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 GH tablets or granules 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 Esomeprazole GH?

Warnings

Do not use Esomeprazole GH if:

- you are allergic to esomeprazole magnesium trihydrate, 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 protonpump 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 Esomeprazole GH 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 GH.

Check with your doctor or pharmacist 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 GH that reduces stomach acid.

There is no evidence that Esomeprazole GH 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?. 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.

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

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

Do not take Esomeprazole GH 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:

Esomeprazole GH 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 GH is not recommended in these patients..

[Relevant condition-specific or medicine-specific subheading(s)]

- This refers to any medical condition-specific, medicine-specific, and/or age-specific subheading(s) relevant for inclusion for certain categories/groups of users, as applicable to the medicine.

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 Esomeprazole GH if you are taking the following medicines:

- atazanavir and nelfinavir - medicines used to treat viral infections such as HIV;
- cilostazol - a medicine used to treat intermittent claudication.

Some medicines may interfere with Esomeprazole GH 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 GH 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 Esomeprazole GH.

4. How do I use Esomeprazole GH?

How much to take

- Take one Esomeprazole GH tablet each day, unless your doctor has told you otherwise.
- The dose of Esomeprazole GH 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 / use Esomeprazole GH

- Esomeprazole GH should be used at about the same time each day.
- Keeping a regular time for taking Esomeprazole GH will help to remind you to take it.
- Esomeprazole GH can be taken with food or on an empty stomach.

- Keep taking Esomeprazole GH for as long as your doctor recommends.
- In most patients, Esomeprazole GH relieves symptoms rapidly and healing is usually complete within 4 weeks.

How to [insert appropriate verb] Esomeprazole GH (relevant for devices)

Swallow Esomeprazole GH 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 Esomeprazole GH

Esomeprazole GH 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 use too much Esomeprazole GH

If you think that you have used too much Esomeprazole GH, 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 Esomeprazole GH?

Things you should do

Take Esomeprazole GH 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 Esomeprazole GH.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Esomeprazole GH.

Tell your doctor if you become pregnant while you are taking Esomeprazole GH.

Tell your doctor if your symptoms return.

Although Esomeprazole GH 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 GH, 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 Esomeprazole GH affects you.

Looking after your medicine

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

Follow the instructions on 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.

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 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>
<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 • 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>Speak to your doctor immediately if you have any of these side effects.</p> <p>These side effects may require medical attention.</p>

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 including yellowing of the skin or eyes, 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 Esomeprazole GH • you begin to vomit blood or food • you pass black (blood-stained) motions 	<p>Contact your doctor immediately if you notice any</p>

Serious side effects	What to do
	of these side effects.

Occasionally, Esomeprazole GH 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.

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 GH contains

Active ingredient (main ingredient)	Esomeprazole magnesium trihydrate
Other ingredients (inactive ingredients)	Non Pareil Seeds 40-50 (PI 108808) Hyprolose Crospovidone Icing sugar with maize starch (PI 109216) Magnesium oxide-light Purified talc Macrogol 6000 Methacrylic acid- ethyl acrylate copolymer (1:1) Glycerol Macrogol 400 Polysorbate 80 Hypromellose phthalate Microcrystalline cellulose Povidone Pregelatinised maize starch

	<p>Silicon dioxide</p> <p>OPADRY complete film coating system 03B54193 PINK (PI 108604)</p> <p>OPADRY complete film coating system 03B84893 PINK (PI 108603)</p> <p>Iron oxide red</p> <p>Iron oxide yellow</p>
Potential allergens	Sugars

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

What Esomeprazole GH looks like

Esomeprazole GH enteric-coated tablet 20 mg are light pink coloured, oblong, biconvex, coated tablets debossed with '20' on one side and 'CE' on the other. [AUST R 307865 (blister pack) and AUST R 307868 (HDPE pack)].

Esomeprazole GH enteric-coated tablet 40 mg are pink coloured, oblong, biconvex, coated tablets debossed with '40' on one side and 'CE' on the other side. [AUST R 307866 (blister pack) and AUST R 307867 (HDPE pack)].

Who distributes Esomeprazole GH

Generic Health Pty Ltd

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