

ESOCOLAM

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 ESOCOLAM?

ESOCOLAM contains the active ingredient esomeprazole magnesium. ESOCOLAM 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, Bleeding Peptic Ulcers.

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

2. What should I know before I use ESOCOLAM?

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

3. What if I am taking other medicines?

Some medicines may interfere with ESOCOLAM 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 ESOCOLAM?

ESOCOLAM 20 or 40 Enteric Coated Tablets

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

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

5. What should I know while using ESOCOLAM?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using ESOCOLAM.
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.
Drinking alcohol	<ul style="list-style-type: none">• Avoid alcohol when taking this medicine.
Looking after your medicine	<ul style="list-style-type: none">• Keep your ESOCOLAM in the blister pack 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 ESOCOLAM?](#) in the full CMI.

6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see the full CMI for more details). The most common side effects are , nausea or vomiting, constipation, diarrhea, headache, wind, stomach pain, skin rash, itchy skin, dizziness, dry mouth and serious side effects are 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.

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.

ESOCOLAM

Esomeprazole(as magnesium)

Consumer Medicine Information (CMI)

This leaflet provides important information about using ESOCOLAM. **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 ESOCOLAM.**

Where to find information in this leaflet:

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

1. Why am I using ESOCOLAM ?

ESOCOLAM contains the active ingredient esomeprazole magnesium. ESOCOLAM is 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.

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

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

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

ESOCOLAM 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 ESOCOLAM with antibiotics. When ESOCOLAM 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

ESOCOLAM 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 ESOCOLAM tablets 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 ESOCOLAM ?

Warnings

Do not use ESOCOLAM 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.
- any medicines containing a proton-pump inhibitor.

Check with your doctor if you:

- have any other medical conditions
 - any problems with your liver
 - severe kidney problems
 - any other medical conditions
 - been diagnosed with osteoporosisif you have ever had a skin reaction after treatment with a medicine similar to ESOCOLAM 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.

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

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

Children younger than 1 year:

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

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 ESOCOLAM 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 ESOCOLAM and affect how it works.

- 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

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 ESOCOLAM.

4. How do I use ESOCOLAM ?

How much to take

- Take one ESOCOLAM tablet each day, unless your doctor has told you otherwise.
- The dose of ESOCOLAM 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 ESOCOLAM until your doctor tells you to stop.
- Swallow ESOCOLAM tablets whole with a glass of water. Do not crush or chew the tablets.

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.

When to take ESOCOLAM

- ESOCOLAM should be used at about the same
- time each day.
- Keeping a regular time for taking ESOCOLAM will help to remind you to take it.

How to take ESOCOLAM

Swallow ESOCOLAM tablets whole with a glass of water. Do not crush or chew the tablets. ESOCOLAM can be taken with food or on an empty stomach.

How long to take ESOCOLAM

Keep taking ESOCOLAM for as long as your doctor recommends.

In most patients, ESOCOLAM relieves symptoms rapidly and healing is usually complete within 4 weeks. Continue taking ESOCOLAM for as long as your doctor tells you to.

If you forget to use ESOCOLAM

ESOCOLAM 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 ESOCOLAM

If you think that you have used too much ESOCOLAM, 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 ESOCOLAM ?

Things you should do

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

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.

Drinking alcohol

Avoid alcohol when taking this medicine.

Looking after your medicine

- Keep your ESOCOLAM in the blister pack until it is time to take it.
- Keep it in a cool, dry place where the temperature stays 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 it where young children cannot reach it.

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 about side effects.

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 • blood in the urine • skin reaction, especially in sunexposed areas, with joint pain 	<p>Speak to your doctor if you have any of these side effects.</p> <p>These side effects may require medical attention.</p>
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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 • 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>
<ul style="list-style-type: none"> • pain or indigestion during treatment with ESOCOLAM • you begin to vomit blood or food • you pass black (blood-stained) Motions 	<p>Contact your doctor immediately if you notice any of these 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.

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 ESOCOLAM contains

Active ingredient (main ingredient)	esomeprazole (as magnesium)
Other ingredients (inactive ingredients)	Tablets: Non Pareil Seeds 40-60 (Proprietary ingredient # 108075), ethylcellulose, magnesium stearate, povidone, light magnesium oxide, methacrylic acid - ethyl acrylate copolymer (1:1), diethyl phthalate, talc, silicified microcrystalline cellulose, lactose monohydrate , maize starch , copovidone, macrogol 8000, crospovidone, colloidal anhydrous silica, hypromellose, titanium dioxide, iron oxide red, OPACODE monogramming ink S-1-17823 BLACK (Proprietary ingredient # 12108)

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

What ESOCOLAM looks like?

ESOCOLAM 20 enteric coated tablets: Brick red coloured, round shape, biconvex, entericcoated tablets, imprinted with "20" on one side with black ink and plain on other side. (Aust R 357775).

ESOCOLAM 40 enteric coated tablets: Brick red coloured, round shape, beveled edge, biconvex, enteric coated tablets, imprinted with "40" on one side with black ink and plain on other side. (Aust R 357796).

ESOCOLAM tablets are available in blister packs (OPA/Al/PVC-Al) of 7, 14, 28 and 30 tablets.

Who distributes ESOCOLAM

Torrent Australasia Pty Ltd
Coleman & Greig, Level 9, 10 George Street
PARRAMATTA WESTFIELD NSW 2150.

This leaflet was prepared in JAN 2023.