

Esomeprazole SUN

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 Esomeprazole SUN?

Esomeprazole SUN contains the active ingredient esomeprazole sodium. Esomeprazole SUN is used to treat Reflux Oesophagitis, Bleeding Peptic Ulcers and Upper gastrointestinal symptoms associated with non-steroidal anti-inflammatory drugs (NSAIDs) therapy. Esomeprazole SUN will only be used if you are unable to take tablets.

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

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

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

3. What if I am taking other medicines?

Some medicines may interfere with Esomeprazole SUN 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 SUN?

- Esomeprazole SUN can be either injected into a vein over a period of at least 3 minutes for adults or injected slowly over a period of 10 to 30 minutes in either adults or children. It must only be given by a nurse or doctor.
- The dosage and the period of time over which it is given will depend on your condition. Your doctor will have had experience injecting Esomeprazole SUN and will choose the best dose for you.

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

5. What should I know while using Esomeprazole SUN?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Esomeprazole SUN.• Tell your doctor or nurse as soon as possible if you do not feel well while you are being given Esomeprazole SUN.
Things you should not do	<ul style="list-style-type: none">• Do not stop using Esomeprazole SUN suddenly, unless you have discussed this with your doctor.
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 SUN affects you.
Looking after your medicine	<ul style="list-style-type: none">• Esomeprazole SUN will be stored by your doctor or pharmacist under the recommended conditions.

For more information, see Section [5. What should I know while using Esomeprazole SUN?](#) 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 constipation, nausea or vomiting, diarrhoea, headache, wind, stomach pain, skin rash, itchy skin, injection site reaction such as redness, discomfort or swelling, dizziness and dry mouth.

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 SUN

Active ingredient: *esomeprazole sodium*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Esomeprazole SUN?

Esomeprazole SUN contains the active ingredient esomeprazole sodium. Esomeprazole SUN is a type of medicine called a proton-pump inhibitor. Esomeprazole SUN 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 SUN is used to treat reflux oesophagitis or reflux disease in the short-term. 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.

Bleeding Peptic Ulcers

Peptic ulcers are ulcers in the stomach or duodenum (tube leading out from the stomach). When these ulcers become severe enough, they start to bleed.

In adults, Esomeprazole SUN can be injected into your veins to treat these bleeding ulcers. Treatment with Esomeprazole SUN should be followed with other therapy to reduce the amount of acid made by the stomach. This is to help your ulcer/s to heal.

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

In adults, if you are unable to eat or drink Esomeprazole SUN may be given to treat the symptoms of pain or discomfort in the stomach caused by NSAIDs (medicines used to treat pain or inflammation). Esomeprazole SUN may also be used to help and prevent ulcers caused by NSAIDs.

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

Warnings

Do not use Esomeprazole SUN if:

- you have allergies to esomeprazole sodium, 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 have allergies to any medicines containing a proton-pump inhibitor.

Some of the symptoms of an allergic reaction may include:

- skin rash
- difficulty in breathing
- hayfever
- feeling faint

Do not use Esomeprazole SUN if you are taking atazanavir or cilostazol.

Please check with your doctor or pharmacist if you are taking these medicines. These medicines will be affected by Esomeprazole SUN.

Check with your doctor if you have:

- allergies to any other medicines, foods, dyes or preservatives
- any other medical conditions; e.g. liver disease
- been diagnosed with osteoporosis
- ever had a skin reaction after treatment with a medicine similar to Esomeprazole SUN that reduces stomach acid

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 use Esomeprazole SUN if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

It is not known if it is safe for you to be given Esomeprazole SUN while you are pregnant. It may affect your baby.

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

Children younger than 1 year

There is no specific information about use in children, so Esomeprazole SUN is not recommended in children.

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 use Esomeprazole SUN if you are taking the following medicines:

- atazanavir and nelfinavir - medicines used to treat Human Immunodeficiency Virus (HIV)
- cilostazol - a medicine used to treat intermittent claudication

Some medicines may interfere with Esomeprazole SUN and affect how it works. These include:

- phenytoin - a medicine used to treat epilepsy
- warfarin and clopidogrel - medicines used to prevent blood clots
- diazepam - a medicine used to treat anxiety and some other conditions
- ketoconazole, itraconazole and voriconazole - medicines used to treat fungal infections
- citalopram, clomipramine and imipramine - medicines used to treat depression
- St John's wort - a herbal remedy used to treat mood disorders
- clarithromycin, erythromycin and rifampicin - medicines used to treat bacterial infections
- 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 SUN 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.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while you are being given Esomeprazole SUN.

If you have not told your doctor about any of these things, tell them before you are given Esomeprazole SUN.

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 SUN.

4. How is Esomeprazole SUN given to you?

How you are given Esomeprazole SUN

Esomeprazole SUN can be either injected into a vein over a period of at least 3 minutes for adults or injected slowly over a period of 10 to 30 minutes in either adults or children. This is called an intravenous infusion. In adults, Esomeprazole SUN can be infused slowly over a longer period of 3 days.

The dosage and the period of time over which it is given will depend on your condition.

Your doctor will have had experience injecting Esomeprazole SUN and will choose the best dose for you. They will be willing to discuss this decision with you.

In most patients, Esomeprazole SUN relieves symptoms rapidly and it will be replaced with oral treatment as soon as you are well enough to swallow.

If you miss an appointment to get Esomeprazole SUN

- Call your doctor right away to reschedule your appointment.
- It is very important that you do not miss a dose of this medicine.

If you stop receiving Esomeprazole SUN

- Do not stop treatment with Esomeprazole SUN unless you have discussed this with your doctor.
- If you have any further questions about your treatment, ask your doctor.

5. What should I know while using Esomeprazole SUN?

Things you should do

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given Esomeprazole SUN.

Call your doctor straight away if you:

- have a serious allergic reaction to Esomeprazole SUN. Symptoms may include swelling of your face, lips, tongue or other parts of the body, wheezing or difficulty breathing.

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

Things you should not do

- Do not stop using Esomeprazole SUN suddenly, unless you have discussed this with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Esomeprazole SUN affects you.

Looking after your medicine

- Esomeprazole SUN will be stored by your doctor or pharmacist under the recommended conditions.
- It should be kept in a cool, dry place, out of the reach of children where the temperature stays below 25°C.

Esomeprazole SUN will only be used if the solution is clear, the package is undamaged and the use by (expiry) date marked on the pack has not been passed.

Getting rid of any unwanted medicine

Any Esomeprazole SUN which is not used will be disposed of in a safe manner by your doctor or pharmacist.

Esomeprazole SUN contains no antimicrobial agent. Each Esomeprazole SUN vial is for single use in one patient only. Any remaining contents should be discarded.

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"> constipation nausea or vomiting diarrhoea headache wind stomach pain skin rash, itchy skin injection site reaction such as redness, discomfort or swelling dizziness dry mouth 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

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

Serious side effects	What to do
<ul style="list-style-type: none"> muscle twitching or jerking movements irregular (fast or slow) heartbeat loss of consciousness or awareness 	

Occasionally, Esomeprazole SUN 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.

Some people may get other side effects while being given Esomeprazole SUN.

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 SUN contains

Active ingredient (main ingredient)	esomeprazole sodium
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> disodium edetate sodium hydroxide

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

What Esomeprazole SUN looks like

Esomeprazole SUN is in powder form and has to be mixed with normal saline before injection or infusion.

AUST R 212516

Who distributes Esomeprazole SUN

Sun Pharma ANZ Pty Ltd
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