

Package leaflet: Information for the user

Esomeprazole 20 mg gastro-resistant tablets

Esomeprazole 40 mg gastro-resistant tablets

Esomeprazole

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What this medicine is and what it is used for
2. What you need to know before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine
6. Contents of the pack and other information

1. What this medicine is and what it is used for

Esomeprazole gastro-resistant tablets 20mg & 40mg contains a medicine called esomeprazole. This belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces.

This medicine is used to treat the following conditions:

Adults and young people aged 12 years and above

- 'Gastro-oesophageal reflux disease' (GORD). This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn.
- Ulcers in the stomach or upper part of the gut (intestine) that are infected with bacteria called 'Helicobacter pylori'. If you have this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.

Adults

- Stomach ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). This medicine can also be used to stop stomach ulcers from forming if you are taking NSAIDs.
- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).
- Prolonged treatment after prevention of rebleeding of ulcers with intravenous esomeprazole.

2. What you need to know before you take this medicine

Do not take this medicine:

- if you are allergic to esomeprazole or any of the other ingredients of this medicine (listed in Section 6).
- if you are allergic to other proton pump inhibitor medicines (e.g. pantoprazole, lansoprazole, rabeprazole, omeprazole).
- if you are taking a medicine containing nelfinavir (used to treat HIV).

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine:

- if you have severe liver problems.
- if you have severe kidney problems.

This medicine may hide the symptoms of other diseases. **Therefore, if any of the following happen to you before you start taking this medicine or while you are taking it, talk to your doctor straight away:**

- you lose a lot of weight for no reason and have problems swallowing.
- you get stomach pain or indigestion.
- you begin to vomit food or blood.
- you pass black stools (blood-stained faeces).

If you have been prescribed this medicine “on demand” you should contact your doctor if your symptoms continue or change in character.

Taking a proton pump inhibitor like this medicine, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Other medicines and this medicine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because this medicine can affect the way some medicines work and some medicines can have an effect on this medicine.

Do not take this medicine if you are taking a medicine containing **nelfinavir** (used to treat HIV).

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Atazanavir (used to treat HIV).
- Ketoconazole, itraconazole or voriconazole (used to treat infections caused by a fungus).
- Erlotinib (used to treat cancer).
- Citalopram, imipramine or clomipramine (used to treat depression).
- Diazepam (used to treat anxiety, relax muscles or in epilepsy).
- Phenytoin (used in epilepsy). If you are taking phenytoin, your doctor will need to monitor you when you start or stop taking this medicine.
- Medicines that are used to thin your blood, such as warfarin. Your doctor may need to monitor you when you start or stop taking this medicine.
- Cilostazol (used to treat intermittent claudication – a pain in your legs when you walk which is caused by an insufficient blood supply).
- Cisapride (used for indigestion and heartburn).
- Digoxin (used for heart problems).
- Methotrexate (a chemotherapy medicine used in high doses to treat cancer) – if you are taking a high dose of methotrexate, your doctor may temporarily stop your this medicine treatment.
- Rifampicin (used for treatment of tuberculosis).
- St John’s wort (*Hypericum perforatum*) (used to treat depression).

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as this medicine to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you tell your doctor about any other medicines you are taking.

This medicine with food and drink

You can take your tablets with food or on an empty stomach.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Your doctor will decide whether you can take this medicine during this time.

It is not known if this medicine passes into breast milk. Therefore, you should not take this medicine if you are breast-feeding.

Driving and using machines

This medicine is not likely to affect your ability to drive or use any tools or machines.

This medicine contains sucrose and lactose monohydrate

This medicine contains sucrose and lactose monohydrate, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

3. How to take this medicine

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- this medicine are not recommended for children less than 12 years old.
- If you are taking this medicine for a long time, your doctor will want to monitor you (particularly if you are taking it for more than a year).
- If your doctor has told you to take this medicine as and when you need it, tell your doctor if your symptoms change.

Taking this medicine

- You can take your tablets at any time of the day.
- You can take your tablets with food or on an empty stomach.
- Swallow your tablets whole with a glass of water. Do not chew or crush the tablets. This is because the tablets contain coated pellets which stop the medicine from being broken down by the acid in your stomach. It is important not to damage the pellets.

What to do if you have trouble swallowing the tablets

- If you have trouble swallowing the tablets:
 - Put them into a glass of still (non-fizzy) water. Do not use any other liquids.
 - Stir until the tablets break up (the mixture will not be clear). Then drink the mixture straight away or within 30 minutes. Always stir the mixture just before drinking it.
 - To make sure that you have drunk all of the medicine, rinse the glass very well with half a glass of water and drink it. The solid pieces contain the medicine - do not chew or crush them.
- If you cannot swallow at all, the tablet can be mixed with some water and put into a syringe. It can then be given to you through a tube directly into your stomach ('gastric tube').
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How much to take

- Your doctor will tell you how many tablets to take and how long to take them for. This will depend on your condition, how old you are and how well your liver works.
- The usual doses are given below.

To treat heartburn caused by gastro-oesophageal reflux disease (GORD):

Adults and children aged 12 years or above:

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the usual dose is one tablet of Esomeprazole gastro-resistant tablets 40 mg once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks if your gullet has not yet healed.
- The usual dose once the gullet has healed is one tablet of Esomeprazole gastro-resistant tablets 20 mg once a day.
- If your gullet has not been damaged, the usual dose is one tablet of Esomeprazole gastro-resistant tablets 20 mg each day. Once the condition has been controlled, your doctor may tell you to take your medicine as and when you need it, up to a maximum of one tablet of Esomeprazole gastro-resistant tablets 20 mg each day.

- If you have severe liver problems, your doctor may give you a lower dose.

To treat ulcers caused by *Helicobacter pylori* infection and to stop them coming back:

- Adults and young people aged 12 or above: the usual dose is one tablet of Esomeprazole gastro-resistant tablets 20 mg twice a day for one week.
- Your doctor will also tell you to take antibiotics, for example amoxicillin and clarithromycin.

To treat stomach ulcers caused by NSAIDs (Non-Steroidal Anti-Inflammatory Drugs):

- Adults aged 18 and above: the usual dose is one tablet of Esomeprazole gastro-resistant tablets 20 mg once a day for 4 to 8 weeks.

To prevent stomach ulcers if you are taking NSAIDs (Non-Steroidal Anti-Inflammatory Drugs):

- Adults aged 18 and above: the usual dose is one tablet of Esomeprazole gastro-resistant tablets 20 mg once a day.

To treat too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome):

- Adults aged 18 and above: the usual dose is one tablet of Esomeprazole gastro-resistant tablets 40 mg twice a day.
- Your doctor will adjust the dose depending on your needs and will also decide how long you need to take the medicine for. The maximum dose is 80 mg twice a day.

To be used as prolonged treatment after prevention of rebleeding of ulcers with intravenous esomeprazole:

- Adults aged 18 years and above: the usual dose is one tablet of Esomeprazole gastro-resistant tablets 40 mg once a day for 4 weeks.

If you take more this medicine than you should

If you take more this medicine than prescribed by your doctor, talk to your doctor or pharmacist straight away.

If you forget to take this medicine

- If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the following serious side effects, stop taking this medicine and contact a doctor immediately:

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction).
- Reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be 'Stevens-Johnson syndrome' or 'toxic epidermal necrolysis'.
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems.

These effects are rare (may affect up to 1 in 1,000 people).

Other side effects include:

Common (may affect up to 1 in 10 people)

- Headache.
- Effects on your stomach or gut: diarrhoea, stomach pain, constipation, wind (flatulence).
- Feeling sick (nausea) or being sick (vomiting).

Uncommon (may affect up to 1 in 100 people)

- Swelling of the feet and ankles.
- Disturbed sleep (insomnia).
- Dizziness, tingling feelings such as “pins and needles”, feeling sleepy.
- Spinning feeling (vertigo).
- Dry mouth.
- Changes in blood tests that check how the liver is working.
- Skin rash, lumpy rash (hives) and itchy skin.
- Fracture of the hip, wrist or spine (if this medicine is used in high doses and over long duration).

Rare (may affect up to 1 in 1,000 people)

- Blood problems such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely.
- Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps.
- Feeling agitated, confused or depressed.
- Taste changes.
- Eyesight problems such as blurred vision.
- Suddenly feeling wheezy or short of breath (bronchospasm).
- An inflammation of the inside of the mouth.
- An infection called “thrush” which can affect the gut and is caused by a fungus.
- Liver problems, including jaundice which can cause yellow skin, dark urine, and tiredness.
- Hair loss (alopecia).
- Skin rash on exposure to sunshine.
- Joint pains (arthralgia) or muscle pains (myalgia).
- Generally feeling unwell and lacking energy.
- Increased sweating.

Very rare (may affect up to 1 in 10,000 people)

- Changes in blood count including agranulocytosis (lack of white blood cells).
- Aggression.
- Seeing, feeling or hearing things that are not there (hallucinations).
- Severe liver problems leading to liver failure and inflammation of the brain.
- Sudden onset of a severe rash or blistering or peeling skin. This may be associated with a high fever and joint pains (Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Muscle weakness.
- Severe kidney problems.
- Enlarged breasts in men.

This medicine may in very rare cases affect the white blood cells leading to immune deficiency. If you have an infection with symptoms such as fever with a **severely** reduced general condition or fever with symptoms of a local infection such as pain in the neck, throat or mouth or difficulties in urinating, you must consult your doctor as soon as possible so that a lack of white blood cells (agranulocytosis) can be ruled out by a blood test. It is important for you to give information about your medication at this time.

Not known (frequency cannot be estimated from the available data)

- Inflammation in the gut (leading to diarrhoea).

If you are on this medicine for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

Do not be concerned by this list of possible side effects. You may not get any of them.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed

in this leaflet.

Reporting side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store this medicine

Keep out of the sight and reach of children”

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the label/carton .The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What this medicine contains

- The active substance is esomeprazole magnesium dihydrate.
One gastro-resistant tablet contain 20 mg esomeprazole (as magnesium dihydrate).
One gastro-resistant tablet contain 40 mg esomeprazole (as magnesium dihydrate).
- The other ingredients are:
- *Pellets*: Hypromellose, sucrose, maize starch, liquid glucose, Talc,
- Methacrylic acid – Ethylacrylate copolymer (1:1) Dispersion 30 % , Sodium Laurilsulfate, Polysorbate 80, Triethyl citrate, Macrogol, Microcrystalline cellulose , Crospovidone, Hypromellose , Stearyl alcohol, Silica colloidal anhydrous
- *Tablet Core*: Crospovidone, Lactose monohydrate and cellulose microcrystalline,
- Silica colloidal anhydrous, Magnesium stearate,
- *Tablet coating*:
20 mg
- Hypromellose , Titanium Dioxide (E171), Macrogol & Iron Oxide Red (E172)
40 mg
- Hypromellose , Titanium Dioxide (E171), Macrogol, Iron Oxide Red (E172), Erythrosine Aluminium Lake (E127) & Iron oxide black (E172)

What this medicine looks like and contents of the pack

- Esomeprazole 20 mg gastro-resistant tablets: Pink coloured, capsule shaped, biconvex, film coated tablets debossed ‘20’ on one side and plain on other side. Length: 16.30 ±0.2mm, Breadth: 8.30 ±0.2mm.

- Esomeprazole 40 mg gastro-resistant tablets: Pink coloured, capsule shaped, biconvex film coated tablets debossed '40' on one side and plain on other side. Length: 19.30 ±0.2mm, Breadth: 8.30 ±0.2mm.

- Your tablets will come in packs of:

- Blister package of Plain aluminium Blister foil along with 3 ply Aluminium Laminated Film
20 mg, 40mg: Blister packs of 28 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Cipla (EU) Limited
Hillbrow House, Hillbrow Road,
Esher, Surrey, KT10 9NW,
United Kingdom

Manufacturer

S&D Pharma CZ, spol. s r.o

spol. s r.o., Theodor 28, 273 08 Pchery (Pharmos a.s. facility), Czech republic

Cipla (EU) Limited

20 Balderton Street, London W1K 6TL, United Kingdom

Cipla Europe NV

Uitbreidingstraat 80, 2600 Antwerp, Belgium

This medicinal product is authorised in the Member States of the EEA under the following names:

| Member states | Product name |
|----------------------|--|
| UK | Esomeprazole 20 mg/40 mg gastro-resistant tablets |
| CY | Esomeprazole Cipla 20 mg/ 40 mg γαστροανθεκτικά δισκία |
| IE | Esomeprazole 20 mg/ 40 mg gastro-resistant tablets |
| MT | Esomeprazole 20 mg/ 40 mg gastro-resistant tablets |
| SE | Esomeprazole Cipla 20 mg/ 40 mg enterotabletter |
| PL | Esomeprazole Cipla , 20 mg/ 40 mg, tabletki dojelitowe |
| FI | Esomeprazole Cipla 20 mg/40 mg enterotabletti |
| NO | Esomeprazole Cipla 20 mg/ 40 mg enterotabletter |
| DK | Esomeprazol Cipla 20 mg/ 40 mg enterotabletter |
| RO | Esomeprazol Cipla 20 mg/40 mg comprimate gastro-rezistente |
| BG | Esomeprazole Cipla 20 mg/40 mg стомашно-устойчиви таблетки |
| SK | Esomeprazole Cipla 20 mg/40 mg gastrorezistentné tablety |

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