



ZIM LABORATORIES LIMITED

B-21/22, MIDC Area, Kalmeshwar - 441501, Dist. Nagpur, Maharashtra, India

Product Name : Leaflet of ESOZIM-40
(Esomeprazole Magnesium Delayed-Release Capsules USP 40 mg)

Rwanda

Size : (L) 146.64 x (W) 180 (After fold (L) 36.66 x (W) 180 mm

Date of Preparation : 05/12/2024

Material : 60 GSM, Maplitho paper (Export Quality)

Artwork Code : *PB389/X/XX/XX

Packing Type : Alu-Alu Blister (Bl.Foil + Coldforming Foil)

Dossier Code : R001025/01

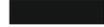
Printing: Front and Back

Language : English

Pack Size : 10 x 10 Capsules

Folding : One Vertical and Two Horizontal

Colour : Black



Black

*PB389/X/XX/XX- Where 'X' is variable and it will be change at the time of commercialised. It is not a part of any regulatory text matter

FRONT SIDE

Patient Information Leaflet

ESOZIM 40

(Esomeprazole Magnesium Delayed Release Capsule USP 40mg)

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 symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- What ESOZIM 40 is and what it is used for
- Before you take ESOZIM 40
- How to take ESOZIM 40
- Possible side effects
- How to store ESOZIM 40
- Contents of the pack and other information

a) What ESOZIM 40 is and what it is used for

Esomeprazole capsules contain 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. Esomeprazole capsules are used to treat the following conditions:

Adults:

- **Gastro-oesophageal reflux disease' (GERD).** 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
- **stomach ulcers caused by medicines called NSAIDs** (Non-Steroidal Anti-Inflammatory Drugs). Esomeprazole capsules 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

Adolescents aged 12 years and above

- **Gastro-oesophageal reflux disease' (GERD).** 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. infections in the urinary tract

b) What you need to know before you take ESOZIM 40

Do not take Esomeprazole capsules if you

- are allergic to esomeprazole or any of the other ingredients of this medicine (listed in Section f)
 - are allergic to other proton pump inhibitor medicines (e.g. pantoprazole, lansoprazole, rabeprazole, omeprazole)
 - are taking a medicine containing nelfinavir (used to treat HIV infection).
- Do not take Esomeprazole capsules if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Esomeprazole capsules.

Warnings and precautions

Talk to your doctor or pharmacist before taking Esomeprazole capsules if you:

- have **severe liver problems**
- have **severe kidney problems**
- have ever had a skin reaction after treatment with a medicine similar to Esomeprazole capsules that reduces stomach acid
- you are due to have a specific blood test (Chromogranin A).

If you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with Esomeprazole capsules. Remember to also mention any other ill effects like pain in your joints.

Esomeprazole capsules may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking Esomeprazole capsules 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 Esomeprazole capsules "on demand" you should contact your doctor if your symptoms continue or change in character.

Talk to your doctor if you experience severe or persistent diarrhoea; esomeprazole has been associated with a small increased risk of infectious diarrhoea.

When taking Esomeprazole capsules, inflammation in your kidney may occur. Signs and symptoms may include decreased volume of urine or blood in your urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness. You should report such signs to the treating physician.

Taking a proton pump inhibitor like Esomeprazole Capsules, 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).

Children under the age of 12 years

Esomeprazole Capsules should not be used in children younger than 12 years. More appropriate pharmaceutical forms of this medicine may be available.

Other medicines and Esomeprazole capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription. This is because Esomeprazole capsules can affect the way some medicines work and some medicines can have an effect on Esomeprazole capsules. **Do not take** Esomeprazole capsules if you are taking a medicine containing **nelfinavir** (used to treat HIV infection).

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

- **atazanavir or saquinavir** (used to treat HIV infection).
- **clopidogrel** (used to prevent blood clots)
- **ketoconazole, itraconazole or voriconazole** (used to treat infections caused by a fungus).
- **erlotinib** (used to treat cancer).
- **citralopram, 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 Esomeprazole capsules
- medicines that are used to thin your blood, such as **warfarin**. Your doctor may need to monitor you when you start or stop taking Esomeprazole capsules.
- **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 Esomeprazole capsules treatment.
- **tacrolimus** (organ transplantation)
- **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 Esomeprazole capsules to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you tell your doctor about any other medicines you are taking.

Esomeprazole capsules with food and drink

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

Pregnancy, breast-feeding and fertility

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 Esomeprazole capsules during this time.

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

Driving and using machines

Esomeprazole capsules are not likely to affect your ability to drive or use any tools or machines. However, side effects such as dizziness and blurred vision may uncommonly or rarely occur (see section d). If affected, you should not drive or use machines.

Esomeprazole capsules contain sucrose and mannitol

- Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.
- Mannitol may have a mild laxative effect.

c) How to take ESOZIM 40

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

- 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.

How much to take

Your doctor will tell you how many capsules 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 recommended doses are given below.

Use in adults aged 18 and above

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

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the recommended dose is one capsule of Esomeprazole 40mg 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 recommended dose once the gullet has healed is one capsule of Esomeprazole 20mg once a day
- If your gullet has not been damaged, the recommended dose is one capsule Esomeprazole 20mg 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 capsule of Esomeprazole 20mg 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:

- The recommended dose is one capsule of Esomeprazole 20mg twice a day for one week
- Your doctor will also tell you to take antibiotics for example amoxicillin and clarithromycin

180 mm

146.64 mm



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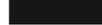
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To treat stomach ulcers caused by NSAIDs (Non-Steroidal Anti-Inflammatory Drugs):

- The recommended dose is one capsule of Esomeprazole 20mg once a day for 4 to 8 weeks.

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

- The recommended dose is one capsule of Esomeprazole 20mg once a day.

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

- The recommended dose is one capsule of Esomeprazole 40mg 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 80mg twice a day.

Prolonged treatment after prevention of rebleeding of ulcers with intravenous Esomeprazole:

- The recommended dose is one capsule of Esomeprazole 40mg once a day for 4 weeks.

Use in adolescents aged 12 or above

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

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the recommended dose is one capsule of Esomeprazole 40mg 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 recommended dose once the gullet has healed is one capsule of Esomeprazole 20mg once a day.
- If your gullet has not been damaged, the recommended dose is one capsule Esomeprazole 20mg 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 capsule of Esomeprazole 20mg 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:

- The recommended dose is one capsule of Esomeprazole 20mg twice a day for one week.
- Your doctor will also tell you to take antibiotics, for example amoxicillin and clarithromycin.

Taking this medicine

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

What to do if you have trouble swallowing the capsules

- If you have trouble swallowing the capsules:
 - Open the capsule carefully above half a glass of still (non-fizzy) water and empty the content of the capsule (granules) into the glass. Do not use any other liquids.
 - Stir. 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 content of the capsule 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 ('gastro tube').

Children under the age of 12 years

Esomeprazole capsules should not be used in children younger than 12 years. More appropriate pharmaceutical forms of this medicine may be available.

Elderly

Dose adjustment is not required in the elderly.

If you take more Esomeprazole capsules than you should

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

If you forget to take Esomeprazole capsules

- 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.

d) 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 Esomeprazole capsules 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 'erythema multiforme', 'Stevens-Johnson syndrome' or 'toxic epidermal necrolysis'.
- yellow skin, dark urine and tiredness which can be symptoms of liver problems.

These side effects are rare, and 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)
- benign polyps in the stomach.

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 Esomeprazole capsules are 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) (see *below)
- 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

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

- inflammation in the gut (leading to diarrhoea)
- If you are on Esomeprazole capsules 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.
- rash, possible with pain in the joints

*Esomeprazole capsules 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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

e) How to Store ESOZIM 40

Store at a temperature not exceeding 30°C, protect from moisture. Keep out of the reach and sight of children.

f) Contents of the pack and other information

What ESOZIM 40 contains

The active ingredient is Esomeprazole magnesium trihydrate.

Each hard gelatin capsule contains
Esomeprazole 40 mg
(As Esomeprazole Magnesium Trihydrate USP)
(As enteric coated pellets)

The capsule also contains: Mannitol, Sucrose, Sodium Lauryl Sulphate, Disodium Hydrogen Phosphate, Sodium Carbonate, Povidone 30, Hypromellose, Methacrylic Acid and Ethyl Acrylate Copolymer Dispersion, Diethyl phthalate, Titanium Dioxide, Purified Talc, N.P. Seeds, Empty Hard Gelatin Capsule size '1'.

What ESOZIM 40 looks like and contents of the pack

ESOZIM 40 is Orange/ clear transparent, Size '1' hard gelatin capsule filled with white to off white enteric coated pellets.

The product is available in:
10x10 Hard Gelatin Capsules in Alu-Alu Blister Pack.

Marketing Authorization Holder and Manufacturer:

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