

ESOPRAZOLE-40

ESOMEPRAZOLE MAGNESIUM TABLETS 40 MG

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 ESOPRAZOLE-40 is and what it is used for
2. What you need to know before you take ESOPRAZOLE-40
3. How to take ESOPRAZOLE-40
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1. What ESOPRAZOLE-40 is and what it is used for
ESOPRAZOLE-40 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.

ESOPRAZOLE-40 is used to treat the following conditions:

Adults

- Gastroesophageal 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). ESOPRAZOLE-40 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 ESOPRAZOLE-40.

Adolescents aged 12 years and above

- Gastroesophageal 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.

2. What you need to know before you take ESOPRAZOLE-40

Do not take ESOPRAZOLE-40:

- If you are allergic to esomeprazole or any of the other ingredients of this medicine.
- 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 infection).

Do not take ESOPRAZOLE-40 if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking ESOPRAZOLE-40.

Warnings and precautions

- Talk to your doctor or pharmacist before taking ESOPRAZOLE-40:
- If you have severe liver problems.
- If you have severe kidney problems.

ESOPRAZOLE-40 may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking ESOPRAZOLE-40 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 ESOPRAZOLE-40 “on demand” you should contact your doctor if your symptoms continue or change in character.

Taking a proton pump inhibitor like ESOPRAZOLE-40, 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).

Other medicines and ESOPRAZOLE-40

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 ESOPRAZOLE-40 can affect the way some medicines work and some medicines can have an effect on ESOPRAZOLE-40.

Do not take ESOPRAZOLE-40 Tablets 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 (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).
- 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 ESOPRAZOLE-40.
- Medicines that are used to thin your blood, such as warfarin. Your doctor may need to monitor you when you start or stop taking ESOPRAZOLE-40.
- 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 ESOPRAZOLE-40 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 ESOPRAZOLE-40 to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you tell your doctor about any other medicines you are taking.

ESOPRAZOLE-40 with food and drink

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

Pregnancy, breast-feeding and fertility

If you are pregnant, 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 ESOPRAZOLE-40 during this time. It is not known if ESOPRAZOLE-40 passes into breast milk. Therefore, you should not take ESOPRAZOLE-40 if you are breastfeeding.

Driving and using machines

ESOPRAZOLE-40 is not likely to affect you being able to drive or use any tools or machines. However, side effects such as dizziness and blurred vision may uncommonly or rarely occur. If affected, you should not drive or use machines.

ESOPRAZOLE-40 contains sucrose

ESOPRAZOLE-40 contains sugar spheres which contain sucrose, 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 ESOPRAZOLE-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 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 recommended doses are given below.

Adults aged 18 and above

To treat heartburn caused by gastroesophageal reflux disease (GERD):

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the recommended dose is one ESOPRAZOLE-40 40 mg gastro-resistant tablet 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 ESOPRAZOLE-40 20 mg gastro-resistant tablet once a day
- If your gullet has not been damaged, the recommended dose is one ESOPRAZOLE-40 20 mg gastro-resistant tablet 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 ESOPRAZOLE-40 20 mg gastro-resistant tablet 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 ESOPRAZOLE-40 20 mg gastro-resistant tablet 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):

- The recommended dose is one ESOPRAZOLE-40 20 mg gastro-resistant tablet 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 ESOPRAZOLE-40 20 mg gastro-resistant tablet 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 ESOPRAZOLE-40 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.

Prolonged treatment after prevention of re-bleeding of ulcers with intravenous ESOPRAZOLE-40:

- The recommended dose is one ESOPRAZOLE-40 40 mg tablet once a day for 4 weeks.

Adolescents aged 12 or above

To treat heartburn caused by gastroesophageal reflux disease (GERD):

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the recommended dose is one ESOPRAZOLE-40 40 mg gastro-resistant tablet 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 ESOPRAZOLE-40 20 mg gastro-resistant tablet once a day.

- If your gullet has not been damaged, the recommended dose is one ESOPRAZOLE-40 20 mg gastro-resistant tablet 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 ESOPRAZOLE-40 20 mg gastro-resistant tablet 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 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 drink 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.

Children under the age of 12 years

ESOPRAZOLE-40 gastro-resistant tablets are not recommended for children less than 12 years old.

Information on dosing for children aged 1 to 11 years is provided in ESOPRAZOLE-40 sachet product information (ask your doctor or pharmacist if you require further information).

Older people

Dose adjustment is not required in the elderly.

If you take more ESOPRAZOLE-40 than you should

If you take more ESOPRAZOLE-40 than prescribed by your doctor, talk to your doctor or pharmacist straight away.

If you forget to take ESOPRAZOLE-40

- 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 ESOPRAZOLE-40 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, 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).

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 ESOPRAZOLE-40 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.

5. How to store ESOPRAZOLE-40

- Keep this medicine out of the sight and reach of children.
- Do not store above 30°C.
- Do not use this medicine after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

- Store this medicine in the original package (blister) or keep the bottle tightly closed in order to protect from moisture.
- Do not throw away any medicines 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 ESOPRAZOLE-40 contains

The active substance is esomeprazole. It also contains the following inactive ingredients: Microcrystalline Cellulose, Croscarmellose Sodium, Magnesium Stearate, Purified Talc, Colloidal Anhydrous Silica, Colorezy White (Seal Coat), Isopropyl Alcohol, Methylene chloride, Enteric coat Red iron oxide, Isopropyl Alcohol, Methylene chloride

What ESOPRAZOLE-40 looks like and contents of the pack

1 x10 Tablets Alu Alu Blister pack

Manufacturers:

STALLION LABORATORIES PVT. LTD.
C-1B, 305/2, 3, 4 & 5, G.I.D.C. KERALA (BAVLA),
DIST.: AHMEDABAD,
GUJARAT, INDIA.