

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.



ESSO 20 mg gastro-resistant capsules, hard
ESSO 40 mg gastro-resistant capsules, hard
Esomeprazole

What is in this leaflet

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

1. What ESSO is and what it is used for

ESSO contains a medicine called esomeprazole, which belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces.

ESSO is used to treat the following conditions:

Adults

- 'Gastroesophageal reflux disease' (GERD). This is where acid from the stomach escapes into the gullet.
- Ulcers in the stomach or upper part of the gut (intestine) that are infected with bacteria called 'Helicobacter pylori'.
- Zollinger-Ellison syndrome - too much acid in the stomach caused by a growth in the pancreas
- Stomach ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). **ESSO** can also be used to stop stomach ulcers from forming if you are taking NSAIDs.
- Prolonged treatment after prevention of rebleeding of ulcers with intravenous esomeprazole.

Adolescents aged 12 years and above

- 'Gastroesophageal reflux disease' (GERD). This is where acid from the stomach escapes into the gullet
- 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 ESSO

Do not take ESSO:

- 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 **ESSO** if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking **ESSO**.

Warnings and precautions

Talk to your doctor or pharmacist before taking ESSO:

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

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

Taking a proton pump inhibitor like **ESSO**, 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 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 **ESSO**. Remember to also mention any other ill-effects like pain in your joints.

Other medicines and ESSO

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 **ESSO** can affect the way some medicines work and some medicines can have an effect on **ESSO**.

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

ESSO 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 **ESSO** during this time.

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

Driving and using machines

ESSO is 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 4). If affected, you should not drive or use machines.

ESSO contains sucrose and mannitol.

- If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.
- Mannitol can cause laxative effect.

3. How to take ESSO

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

- **ESSO** is 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 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.

What to do if you have trouble swallowing the capsules

- If you have trouble swallowing the capsules:
 - 1) Open the capsule carefully above a glass of still (non-fizzy) water and empty the content of the capsule (granules) into the glass. Do not use any other liquids.
 - 2) Stir. Then drink the mixture straight away or within 30 minutes. Always stir the mixture just before drinking it.
 - 3) 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 ('gastric tube').

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 and how well your liver works.
- The recommended doses are given below.

Adults aged 18 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 capsule of **ESSO 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 recommended dose once the gullet has healed is one capsule of **ESSO 20 mg** once a day.
- If your gullet has not been damaged, the recommended dose is one capsule **ESSO 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 capsule of **ESSO 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 children aged 12 or above: the recommended dose is one capsule of **ESSO 20 mg** twice a day for one week.
- Your doctor will also tell you to take antibiotics called amoxicillin and clarithromycin.

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

- Adults aged 18 and above: the recommended dose is one capsule of **ESSO 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 treat stomach ulcers caused by NSAIDs (Non-Steroidal Anti-Inflammatory Drugs):

- Adults aged 18 and above: the recommended dose is one capsule of **ESSO 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 recommended dose is one capsule of **ESSO 20 mg** once a day.

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

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

Use in 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 **ESSO 40 mg** gastro-resistant capsule 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 **ESSO 20 mg** gastro-resistant capsule once a day.
- If your gullet has not been damaged, the recommended dose is one **ESSO 20 mg** gastro-resistant capsule 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 **ESSO 20 mg** gastro-resistant capsule twice a day for one week.
- Your doctor will also tell you to take antibiotics for example amoxicillin and clarithromycin.

Children under the age of 12 years

ESSO capsules are not recommended for children less than 12 years old.

Renal impairment

Dose adjustment is not required in patients with impaired renal function.

Hepatic impairment

Dose adjustment is not required in patients with mild to moderate liver impairment. For patients with severe liver impairment, a maximum dose of 20 mg **ESSO** should not be exceeded.

Elderly

Dose adjustment is not required in the elderly.

If you take more ESSO than you should

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

If you forget to take ESSO

- 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 **ESSO** and contact a doctor immediately:

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties to swallow (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, affecting less than 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: diarrhea, 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 **ESSO** 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.

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

- If you are on **ESSO** 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.
- Inflammation in the gut (leading to diarrhea).
- Rash, possibly with pain in the joints.

ESSO 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 or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store ESSO

- Keep this medicine out of the sight and reach of children.
- Do not store above 30°C.
- Keep this medicine in the original container (blister).

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

6. Contents of the pack and other information

What ESSO contains

• The active substance is esomeprazole.

ESSO capsules come in two strengths containing 20 mg or 40 mg of esomeprazole (as magnesium dihydrate).

The other ingredients are: mannitol, sucrose, disodium hydrogen phosphate, calcium carbonate, hydroxypropyl methyl methylcellulose, cetyl alcohol, sodium methyl paraben, sodium propyl paraben.

Wrap: Hard gelatin capsule.

Contents of the pack:

- Box with 14 capsules of 20 mg esomeprazole in blister packs.
- Box with 28 capsules of 20 mg esomeprazole in blister packs.
- Box with 14 capsules of 40 mg esomeprazole in blister packs.
- Box with 28 capsules of 40 mg esomeprazole in blister packs.

Marketing Authorisation Holder and Manufacturer:

ZADA Pharmaceuticals Ltd.
Donji Bistarac without number
75300 Lukavac, Bosnia and Herzegovina.

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