

PATIENT INFORMATION LEAFLET

ESSIUM 40 mg Powder For Solution For I.V. Injection/Infusion Intravenously Administered Sterile

- **Active substance:** Each vial contains 42.5 mg esomeprazole sodium equivalent to 40 mg esomeprazole.
- **Excipient:** Disodium edetate dihydrate, sodium hydroxide (for pH adjustment), water for injection

Before using this medicine, read all of this PATIENT INFORMATION LEAFLET carefully. Because, this leaflet includes important information for you.

- *Keep this PATIENT INFORMATION 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. Do not pass it on to others.*
- *During the use of this medicine, tell that you are using this medicine when you go to a doctor or hospital.*
- *Follow the written instructions exactly. Do not use **higher or lower** dose than the recommended dose.*

The following subjects are covered herein:

- 1. What is ESSIUM and what is it used for?**
- 2. Before you are given ESSIUM?**
- 3. How you will be given ESSIUM?**
- 4. Possible side effects**
- 5. How to store ESSIUM?**

1. What is ESSIUM and what is it used for?

ESSIUM is one of the drugs known as “proton pump inhibitor”. It reduces the acid formation in your stomach.

It contains one dose of dust to prepare ESSIUM 40 mg powder for solution for IV injection/infusion: 40 mg

Each dose is contained in vials containing 40 mg esomeprazole powder.

ESSIUM is applied for treatment of the following:

- Inflammation and pain around esophagus due to gastric juice leak into the esophagus (for the treatment of erosive reflux esophagitis)
- Heartburn and vomiting due to gastric juice leak into the esophagus in adults, adolescents and children (for the symptomatic treatment of gastro-esophageal reflux)
- Ulcers: Improvement and treatment of ulcers caused by drugs used for pain and inflammation in adults (prevention of gastric and duodenal ulcer related to the improvement of gastric ulcers and NSAIDs (non-steroidal anti-inflammatory drugs))
- Short-term stopping and preventing the reoccurrence of bleeding in adult patients with gastric or duodenal ulcer with acute bleeding after therapeutical endoscopy.

2. Before you are given ESSĪUM

DO NOT use ESSĪUM under the following circumstances:

If:

- You have ever experienced an allergic reaction against any drug containing substances that are available in ESSĪUM.
- You are allergic to any other proton pump inhibitors.
- Do not use along with esomeprazole, atazanavir or nelfinavir (drug for HIV treatment) as it is with all the proton pump inhibitors.

USE ESSĪUM with CAUTION if

Before you start using ESSĪUM or during your treatment, for the following conditions consult your doctor:

- You experience any of the below-mentioned cases:
 - Significant weight loss without any reason
 - Pain or indigestion during ESSĪUM treatment
 - Vomiting food or blood
 - Black feces or blood stains in feces

IMMEDIATELY consult your doctor.

Consult your doctor if you have severe liver problems as your doctor might choose to reduce the dose.

Consult your doctor if you have severe kidney problems.

If ESSĪUM is prescribed to be used “when needed”, consult your doctor in the event that symptoms change or become chronic.

Using a proton pump inhibitor such as ESSĪUM especially for more than a year may slightly increase the risk of femoral, ankle or spinal fractures. If you are diagnosed with osteoporosis or using corticosteroids (which may increase osteoporosis risk), consult your doctor.

Decrease in the blood magnesium level (hypomagnesemia) is reported. Your doctor may periodically track the blood magnesium levels before and after the treatment for patients who are expected to have long-term treatment or in case that the drug is used along with other drugs that may cause a decrease in blood magnesium level (e.g. diuretics).

Interactions with examinations on tumors related to secretory glands (neuroendocrine): It may cause false positive results in diagnostic examinations related to neural system and secretory glands due to the drug-induced decreases in gastric acid.

Decrease in gastric acid induced by any reason including proton pump inhibitors causes an increase in the number of bacteria normally available in gastro-intestinal system. Treatment with proton pump inhibitors may slightly increase the gastro-intestinal system inflammations.

Please consult your doctor even if these warnings apply to you at any time in the past.

Pregnancy

Please consult your physician or pharmacist before taking the medicine.

Inform your doctor about your pregnancy or intentions to get pregnant before using ESSÍUM. If you are pregnant, use ESSÍUM only upon the advice of your doctor.

If you realize that you are pregnant during your treatment, immediately consult your physician or pharmacist.

Lactation

Please consult your physician or pharmacist before taking the drug.

Inform your doctor if you are breastfeeding before using ESSÍUM. If you are breastfeeding, use ESSÍUM only upon the advice of your doctor.

Ability to drive and use machines

ESSÍUM is expected to have no effect on the ability to use tools or machines.

Vital information regarding some of the excipients contained in ESSÍUM

The medical product contains 1 mmol sodium (less than 23 mg) each vial, which actually equals to no sodium.

Use in combination with other drugs

ESSÍUM may alter the way of work for some drug products, or some drugs may have an effect on ESSÍUM.

Do not use ESSÍUM if you use any drug containing nelfinavir or atazanavir (used in HIV treatment).

If you are using any of the drugs listed below, consult your doctor or pharmacist:

- Ketoconazole, itraconazole or voriconazole (drugs to prevent fungal inflammation)
- Erlotinip or drugs from the same class (used in cancer treatment)
- Citalopram, imipramine or clomipramine (used in depression treatment)
- Diazepam (used in anxiety treatment, muscle relaxation or epilepsy treatment)
- Phenytoin (used in epilepsy treatment). If you use phenytoin, your doctor needs to observe you during or after ESSÍUM treatment.
- Warfarin or clopidogrel (anticoagulant drugs used as blood thinner). Your doctor needs to observe you during or after ESSÍUM treatment.
- Silostazol (used in intermittent claudication treatment – leg ache occurring during a walk due to the lack of blood circulation)
- Cisapride (used in indigestion and heartburn)
- Digoxin (drug for heart diseases)
- Methotrexate (a high-dose chemotherapy drug used in cancer treatment). If you use high dose methotrexate, ESSÍUM treatment may need temporary pausing.
- Rifampicin (drug for tuberculosis treatment)
- St. John's Wort (*Hypericum perforatum*) (drug for depression treatment)

In case that your doctor prescribes amoxicillin and clarithromycin antibiotics to cure ulcer caused by *Helicobacter pylori*, it has utmost importance that you inform your doctor regarding any other drugs you use.

If you are currently taking or recently took any prescribed or over-the-counter drugs, please inform your physician or pharmacist.

3. How you will be given ESSÍUM

Instructions regarding correct use and dosage/administration frequency:

If you cannot use tablets, a doctor or a nurse is to apply ESSÍUM as injection or infusion up to 10 days. When you are eligible to oral usage, continue your treatment with esomeprazole tablet. The dosage is to be decided by your doctor.

Your doctor establishes and applies the necessary dosage considering your condition.

Method of administration

For the treatment of inflammation and pain around esophagus (erosive reflux esophagitis), the dosage is ESSÍUM 40 mg per day. The total treatment period is 4 to 8 weeks depending on the severity of the disease and your response to the treatment. To prevent recurrence, the recommended dose is ESSÍUM 20 mg once daily.

For the treatment of symptoms such as heartburn and vomiting (for the symptomatic treatment of gastro-esophageal reflux), recommended dosage is ESSÍUM 20 mg per day.

For short-term stopping and preventing the reoccurrence of bleeding in adult patients with gastric or duodenal ulcer with acute bleeding after therapeutical endoscopy.

For adult patients with gastric or duodenal ulcer with acute bleeding after therapeutical endoscopy, 80 mg should be applied as bolus infusion within 30 minutes followed by 8 mg/hour continuous intravenous infusion for 3 days (72 hours).

Various age groups:

Use in children:

ESSÍUM can be used for children between the ages 1-18 and for adolescents.

For children between 1-18:

- The dosage is to be decided by your doctor.
- Common use dosage is 10 or 20 mg per day for children between 1-11.
- Common use dosage is 20 or 40 mg per day for children between 12-18.
- The drug is intravenously applied as injection or infusion. It should be applied within 30 minutes at most.

Use in elderly: ESSÍUM can be used in geriatric groups.

Special usage cases:

Liver failure:

Slight and mild liver failure may cause a damage in esomeprazole degradation. Severe liver failure decreases drug degradation and increase blood levels. Thus, the applied dosage should not exceed 20 mg per day for patients with severe liver failure. During single dosage per day application, esomeprazole or degradation products do not tend to accumulate within body.

Kidney failure:

There is no studies on patients with kidney failure. Esomeprazole degradation is not expected to demonstrate an altered course in patients with kidney failure.

If you have the impression that the effect of ESSĪUM is too strong or weak, talk with your doctor or pharmacist.

If you have taken ESSĪUM than you should have:

If you suspect that you are applied more ESSĪUM than you normally should, you may experience some of the possible side effects listed below, please inform your doctor.

If you have used ESSĪUM more than you should have or more than prescribed consult a physician or a pharmacist.

If you forget to take ESSĪUM:

Do not double-dose to make up for forgotten doses.

4. Possible side effects

As with all drugs, adverse effects may be observed in people sensitive to substances contained by ESSĪUM.

If you experience any of the effects listed below, cease using ESSĪUM and IMMEDIATELY consult your physician or go to the nearest emergency room:

- Sudden stridor, swelling of lips, tongue and throat or any other part of the body, skin rash, fainting or difficulty in swallowing (severe allergic reaction)
- Bubble formation or peeled areas on skin accompanied by rash. It may also cause severe bubble formation and bleeding around lips, eyes, mouth, nose and genital area. It may be “Stevens-Johnson syndrome” or “toxic epidermal necrolysis”.
- Jaundice on skin, dark colored urine and fatigue which are also symptoms of liver diseases.

These are all severe adverse effects, which are rarely (less than 1 in 1000) reported.

The other adverse effects are as follows:

Common (effect on less than 1 in 10)

- Headache
- Effect on stomach or intestines: Diarrhea, abdominal pain, constipation, gas
- Nausea or vomiting
- Reaction on the injection area
- Benign polyps in stomach

Uncommon (effect on less than 1 in 100)

- Swelling of feet and ankles
- Sleep disorders (insomnia)
- Drowsiness, tingling like “prickling”, somnolence
- Dizziness (vertigo)
- Dry mouth
- Changes in blood tests related to liver functions
- Skin rash, skin bumps (urticaria) and itchiness
- Femoral, ankle or spinal fractures (in case high dose ESSiUM is used during long terms)

Rare (effect on less than 1 in 1000)

- Blood problems such as decrease in the number of white blood cells or thrombocytes. It may cause fatigue and bruises or enhances the possibility of infection.
- Low blood sodium levels. It may cause fatigue, nausea and cramps.
- Feeling agitated, confused or depressed
- Gustatory disorders
- Problems in eyesight such as blurred vision
- Sudden stertorous respiration or bronchospasm
- Mouth inflammation
- Fungal inflammation named “moniliasis” which may affect intestinal system
- Icteric or non-icteric hepatitis which may cause jaundice on skin, dark colored urine and fatigue
- Alopecia
- Rash on skin when exposed to sun
- Arthralgia or myalgia
- Feeling sick in general and feebleness
- Increase in perspiration

Very rare (effect on 1 in 10000)

- Changes in blood levels including agranulocytosis (white blood cell deficiency)
- Aggression, short-temperedness
- Seeing, feeling or hearing non-existent phenomena (hallucinations)
- Intestinal inflammation causing diarrhea (microscopic colitis)
- Severe liver problems causing liver failure and brain inflammation
- Sudden skin rash or bubble formation or peeled areas on the skin. This may be related to high fever and arthralgia (Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis)
- Muscle weakness
- Severe kidney diseases
- Gynecomastia
- Decrease in the blood magnesium levels (If you use ESSiUM more than 3 months, it is likely to observe a decrease in your blood magnesium levels. Low magnesium level may cause fatigue, involuntary muscle contractions, disorientation, convulsions, drowsiness or increase in the heart rate. If you experience any of these effects, immediately consult your doctor.)

ESSİUM may effect white blood cells, which are important for immune protection, in very rare cases. If you have infection accompanied by a **severe** general condition such as fever or experience local inflammation such as sore throat, pain in mouth or dysuria along with fever, immediately consult your doctor. Thus, any potential deficiency in white blood cells (agranulocytosis) may be detected by a blood test. It is important that you provide information regarding your treatment at this point.

The list of adverse effects does not necessarily cause any concerns. You may never experience any of the listed symptoms.

There may be reactions on the application area such as tissue inflammation.

If you notice any side effect not mentioned in this leaflet, please inform your doctor or pharmacist.

5. How to store ESSİUM

Keep ESSİUM out of the sight and reach of children, and in its original packaging.

You doctor or hospital stores ESSİUM for infusion/injection. Correct storage, preparation and application falls under the responsibility of the medical personnel.

The product must be immediately used due to microbiological reasons. If not immediately used, the storage duration and conditions during application are under the responsibility of the user and this duration should not exceed 12 hours at 25°C.

Use in compliance with the expiry date.

Do not use ESSİUM after the expiration date printed on its packaging.

If you notice any irregularities in the product and/or its packaging, do not use ESSİUM.

Do not put in trash if the product is expired or out of use. Give it to collection system specified by Ministry of Environment and Urbanization.

Marketing Authorization Holder:

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This patient information leaflet was last approved on 23/05/2018.

INFORMATION PROVIDED HERE AFTER IS INTENDED FOR THE MEDICAL PERSONNEL APPLYING THE DRUG PRODUCT

Prepared solution should be visually examined in terms of particles and colorization before application. Only clear solutions should be used. It is for single use. For 20 mg doses, half of the prepared solution should be used. Unused solutions should be discarded.

Injection 40 mg

Solution for injection (8 mg/ml) is prepared by adding 5 ml 0.9% sodium chloride solution (for intravenous usage) into vial containing esomeprazole 40 mg.

Prepared solution for injection is clear, colorless or slightly yellow.

Infusion 40 mg

Solution for infusion is prepared by dissolving the content of a vial containing esomeprazole 40 mg into up to 100 ml 0.9% sodium chloride solution (for intravenous usage).

Prepared solution for infusion is clear, colorless or slightly yellow.