

**Patient leaflet in accordance with the Pharmacists' Regulations
(Preparations) - 1986**

This medicine is dispensed with a doctor's prescription only

Esoprim S.K. 20 mg

Hard capsules

Active ingredient

Each capsule contains:

esomeprazole 20 mg

(as esomeprazole sodium)

Esoprim S.K. 40 mg

Hard capsules

Each capsule contains:

esomeprazole 40 mg

(as esomeprazole sodium)

Inactive ingredients and allergens: see under 'Important information about some of this medicine's ingredients' and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

In adults, Esoprim S.K. 20 mg and Esoprim S.K. 40 mg are intended for:

Treatment of heartburn with or without inflammation of the gullet caused by reflux of gastric acid. Esoprim S.K. reduces the production of acid and helps heal the gullet by reducing pain and inflammation.

Treatment of ulcers in the upper part of the gut or stomach caused by *Helicobacter pylori* bacteria. Esoprim S.K., in combination with suitable antibiotics, treats the infection, allows the ulcer to heal, and prevents its recurrence.

Treatment of gastric ulcer caused by use of non-steroidal anti-inflammatory drugs (NSAIDs) such as arthritis (rheumatism) medicines.

Prevention of the formation of gastric ulcers, if you might possibly develop them as a result of taking non-steroidal anti-inflammatory drugs (NSAIDs), such as arthritis (rheumatism) medicines.

Prolonged treatment with Esoprim S.K. capsules to prevent recurrent bleeding of a gastric or duodenal ulcer, after initial treatment with intravenous Esomeprazole.

In adolescents over the age of 12, Esoprim S.K. 20 mg is intended for:

Treatment of heartburn (with or without inflammation of the gullet) caused by reflux of gastric acid. Esoprim S.K. reduces the production of acid and helps heal the gullet by reducing pain and inflammation.

Treatment of ulcers in the upper part of the gut or stomach caused by *Helicobacter pylori* bacteria. Esoprim S.K. in combination with suitable antibiotics, treats the infection, allows the ulcer to heal, and prevents its recurrence.

In adolescents over the age of 12, Esoprim S.K. 40 mg is intended for:

- treatment of heartburn (with inflammation of the gullet) caused by reflux of gastric acid. Esoprim S.K. reduces the production of acid and helps heal the gullet by reducing pain and inflammation.

Therapeutic group: proton pump inhibitors (gastric acid pump).

2. Before using this medicine

X Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (listed in section 6).

- You have a known sensitivity to another proton pump inhibitor (medicines for treating ulcer-like symptoms, for example: pantoprazole, lansoprazole, rabeprazole, omeprazole).
- You are being treated with nelfinavir (a medicine to treat Human immunodeficiency virus [HIV]).

Special warnings about using Esoprim S.K.

! Before starting treatment with Esoprim S.K., tell your doctor if:

- You are suffering, or have suffered in the past, from severely impaired liver function.
- You are suffering, or have suffered in the past, from severely impaired kidney function.
- You have suffered in the past from a skin reaction after treatment with a medicine similar to Esoprim S.K., which lowers gastric acidity.
- You are due to have a certain blood test (chromogranin A).

Esoprim S.K. may mask the symptoms of other diseases. **So, if you experience any of the following before or during treatment with Esoprim S.K., consult your doctor immediately:**

- unexplained weight loss or difficulty swallowing
- abdominal pain or indigestion
- vomiting food or blood
- black stools (bloody stools)

If you are taking the medicine as and when you need it (according to a doctor's instructions), please inform your doctor. You must also tell your doctor if there is any change in your symptoms.

There is an increased risk of fracture in the hip, wrist or spine with prolonged use of over a period of one year and more. Please inform your doctor if you have been diagnosed with osteoporosis (bone loss – people with this disease are more prone to fractures) or if you are taking corticosteroids.

- If you have a rash on your skin, especially in areas exposed to the sun, please tell your doctor as soon as possible because you may need to stop treatment with Esoprim S.K. Be sure to also mention to the doctor any other ill-effects like pain in your joints.

Other medicines and Esoprim S.K.

! If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. This is because Esoprim S.K. may affect the way certain medicines work, and certain medicines may affect the way Esoprim S.K. works.

- Do not take Esoprim S.K. if you are being treated with a medicine that contains nelfinavir (a medicine used to treat AIDS [HIV])

Tell your doctor or pharmacist if you are taking:

- atazanavir (used to treat AIDS – HIV)
- medicines for fungal infections (ketoconazole or itraconazole and voriconazole)
- antidepressants (citalopram, imipramine, or clomipramine)
- erlotinib (a medicine to treat cancer)
- sedatives (diazepam)
- medicines for epilepsy (phenytoin). If you are taking phenytoin, your doctor will have to monitor your treatment when you start and when you stop taking Esoprim S.K.
- medicines that are used to thin your blood (warfarin). Your doctor will have to monitor your treatment when you start and when you stop taking Esoprim S.K.
- clopidogrel (used to prevent blood clots)
- medicines for heart problems (digoxin)
- medicine for tuberculosis (rifampicin)
- an antidepressant product: St. John's wort (*Hypericum perforatum*)

- medicines used to treat arterial diseases in the legs that cause non-permanent limp (intermittent claudication) (cilostazol)
- methotrexate (a medicine used in high doses to treat cancer). If you are taking a high dose of methotrexate, your doctor may tell you to temporarily stop your Esoprim S.K. treatment.
- a medicine used to prevent transplant rejection after organ transplantation (tacrolimus)
- certain medicines used to treat malignant tumors (such as erlotinib)
- medicines used to accelerate gastric emptying (cisapride) in combined treatment with Esoprim S.K.

If you are receiving Esoprim S.K. together with clarithromycin and amoxicillin to treat an ulcer caused by *Helicobacter pylori* bacteria, it is important that you tell your doctor about any other medicines you are taking.

! Using Esoprim S.K. and food

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

! Pregnancy and breastfeeding

If you are pregnant, think you are pregnant or are planning to become pregnant, consult your doctor before taking this medicine.

It is not known whether Esoprim S.K. passes into breast milk. Therefore, do not use Esoprim S.K. if you are breastfeeding.

! Driving and using machines

Esoprim S.K. is not expected to affect your ability to drive or use machinery. However, side effects such as dizziness or blurred vision may occur. If you suffer from these side effects, do not drive and do not use machinery.

! Important information about some of this medicine's ingredients

The capsules contain sucrose (a certain type of sugar). If you have been told by your doctor that you cannot digest certain sugars, consult your doctor before taking this medicine.

Esoprim S.K. 20 mg – each capsule contains about 20.0-22.9 mg sucrose.

Esoprim S.K. 40 mg – each capsule contains about 40.0-45.8 mg sucrose.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

The doctor will tell you how to take the medicine (how many capsules to take and when to take them). Your doctor will decide which capsule strength you need and how long to take the treatment depending on the disease you have.

If you are taking this medicine for a long time (particularly if you are taking it for more than a year) your doctor may want to perform certain tests.

If your doctor has told you to take this medicine as and when you need it, tell your doctor if you experience any change in your symptoms.

Do not exceed the recommended dose.

Directions for use

- You can take your capsules at any time of the day.
- You can take your capsule with food or on an empty stomach.
- Swallow the medicine whole, with half a glass of water. Do not chew or crush the content of the capsule. The capsules contain coated granules which prevent the medicine from being broken down by the acid in your stomach so it is important not to crush these granules.
- Patients who have trouble swallowing the capsule, can open the capsule and disperse its content in half a glass of water (do not use carbonated water or any other liquid). Stir well before drinking (the solution will not be clear), drink it straight away or within 30 minutes at the most. To make sure that you have

taken all of the medicine, rinse the glass with some water and drink it. The solid pieces contain the medicine - do not chew or crush them.

Elderly

Dose adjustment is not required in the elderly.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take this medicine at the scheduled time, take a dose as soon as you remember. However, if you remembered when it is almost time for your next dose, do not take the missed dose and take your next dose at the scheduled time.

How can you contribute to the success of your treatment?

Complete the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

Carefully follow the exact instructions for taking this medicine and ask your doctor if you are not sure about anything.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

4. Side effects

Like with all medicines, using Esoprim S.K. may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Side effects that require special attention:

Stop treatment and consult your doctor immediately in the following cases:

- sudden wheezing; shortness of breath; swelling of the lips, tongue and throat, or body; rash; fainting or difficulties in swallowing – these are signs of a severe allergic reaction.
- redness of the skin with blisters or peeling. There may also be blisters and bleeding in the lips, eyes, mouth, nose, and genitals. This could be Stevens-Johnson syndrome or toxic epidermal necrolysis.
- yellowing of the skin and whites of the eyes, dark urine, and tiredness can be symptoms of liver problems.

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

Common side effects, occur frequently (affect up to one patient in 10):

- headache
- diarrhea, abdominal pain, constipation, flatulence
- nausea and vomiting

Uncommon side effects (affect up to one patient in 100):

- swelling of the legs and ankles
- sleeping problems (insomnia)
- dizziness, tingling feeling (pins and needles)
- sleepiness
- spinning feeling (vertigo)
- dry mouth
- changes in liver function blood tests
- skin rash, blistering, and itching
- fractures in the hip, wrist or spine (when using high doses of Esoprim S.K. for a long time)

- elevated liver enzymes

Rare side effects (affect up to one patient in 1,000):

- blood problems such as a reduced number of white cells or platelets - can cause weakness, bruising or increase the risk of infections
- low levels of sodium in the blood - may cause weakness, vomiting, and cramps
- agitation, confusion, depression
- taste changes
- eye problems such as blurred vision
- sudden shortness of breath (bronchospasm)
- mouth infection
- a fungal infection that may affect the gut
- liver problems, including jaundice, that may cause yellowing of the skin, dark urine and tiredness
- hair loss
- skin rash on exposure to sun
- joint pain
- muscle pain
- feeling unwell and lacking energy
- increased sweating

Very rare side effects (affect up to one patient in 10,000):

- sudden onset of a severe rash, skin blistering, or peeling. This may be accompanied by high fever and joint pain (erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis).
- changes in blood count, including agranulocytosis (reduction in white blood cells)
- aggression
- hallucinations
- severe liver problems leading to liver failure and inflammation in the brain
- muscle weakness
- severe kidney problems
- enlarged breasts in men

Side effects whose frequency is not known (frequency cannot be estimated from the available data):

- low magnesium levels in the body: This problem could be serious. Low magnesium levels in the body can happen in certain people who have taken proton pump (gastric acid pump) inhibitor medicines like Esoprim S.K. for at least three months. If your magnesium levels fall, you may get signs of low magnesium levels.

Please inform your doctor immediately if you experience any of the following signs:

- dizziness
 - disorientation
 - fatigue
 - convulsions
 - increased heart rate
 - involuntary muscle contractions
 - low level of magnesium in the blood can cause low blood calcium and/or low blood potassium levels
- If you are required to take Esoprim S.K. for a long time, your doctor may check the magnesium levels in your body before or during treatment with Esoprim SK.
- inflammation in the gut (causes diarrhea)
 - rash, usually with joint pain

In very rare cases, Esoprim S.K. may affect the white blood cells and lead to immune deficiency. If you have an infection with signs such as fever with a severely reduced general condition or fever with signs of a local infection such as pain in the head and neck, throat or mouth, or difficulties in urinating, consult the doctor right away so that a lack of white blood cells (agranulocytosis) can be ruled out by a blood test. You must tell your doctor that you are taking Esoprim S.K.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:

<https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions

- Store below 30°C. Keep this medicine in the original package to protect from moisture.
- Do not store different medicines in the same package.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Capsule contents:

sugar spheres (containing maize starch and sucrose), methacrylic acid-ethyl acrylate copolymer, methyl cellulose, talc, triethyl citrate, titanium dioxide, glycerol monostearate, polysorbate 80

Capsule cap:

hypromellose, titanium dioxide (E171), purified water, potassium chloride, carrageenan, iron oxide red

Capsule body:

hypromellose, titanium dioxide (E171), purified water, potassium chloride, carrageenan, iron oxide red

Imprinting:

black ink.

What the medicine looks like and contents of the pack:

Esoprim S.K. 20 mg capsules: hard, opaque, light pink capsule, with the letters ES imprinted on the cap and the number 20 imprinted on the body of the capsule. The capsule contains spherical granules.

Esoprim S.K. 40 mg capsules: hard, opaque, pink capsule, with the letters ES imprinted on the cap and the number 40 imprinted on the body of the capsule. The capsule contains spherical granules.

Each pack contains 28 capsules (4 trays of 7 capsules).

Registration holder's name and address:

K.S. Kim International Ltd., 94 Yigal Alon, Tel Aviv 6789139.

Manufacturer's name and address:

Esteve Pharmaceuticals,
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This format of this leaflet was determined by the Ministry of Health, and its content conforms to the leaflet reviewed and approved by the Ministry of Health in August 2017 for the original medicinal product and updated on November 2019.

Registration number of the medicine in the Ministry of Health's National Drug Registry:

Esoprim S.K. 20 mg: 162-75-35708

Esoprim S.K. 40 mg: 162-76-35709