

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

This medicine is dispensed without a doctor's prescription

Esoprim Control 20 mg - hard capsules

Composition

Each capsule contains:

Esomeprazole 20 mg (as esomeprazole sodium)

For a list of excipients and allergens – please see section 6 “Additional information” and section “Important information about some of this medicine’s ingredients”.

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

1. What is this medicine intended for?

Esoprim Control is used in adults for the short-term treatment of reflux symptoms (for example, heartburn and acid regurgitation).

Reflux is the backflow of acid from the stomach into the esophagus (“foodpipe”) which may cause inflammation and pain in the esophagus. This may cause you symptoms such as a painful sensation in the chest rising up to your throat (heartburn) and a sour taste in the mouth (acid regurgitation).

Esoprim Control is not meant to bring immediate relief. You may need to take the capsules for 2-3 days in a row before you feel better. You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

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

Esoprim Control contains the active substance esomeprazole. It belongs to a group of medicines called ‘proton pump inhibitors’. They work by reducing the amount of acid that your stomach produces.

2. Before using the 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 the use of this medicine

! Before treatment with Esoprim Control, tell a doctor or a pharmacist if:

- You have had a stomach ulcer or stomach surgery in the past.
- You are taking a treatment continuously for reflux or heartburn for 4 or more weeks.
- You have jaundice (yellowing of skin or eyes) or severe liver problems.
- You have severe kidney problems.
- You are over 55 years old and have new or recently changed reflux symptoms or need to take a non-prescription indigestion or heartburn remedy treatment every day.
- You have ever had a skin reaction after treatment with a medicine similar to Esoprim Control that reduces stomach acid.
- You are due to have an endoscopy or a urea breath test.
- You are due to have a specific blood test (Chromogranin A).

Tell your doctor immediately before or after taking this medicine, if you notice any of the following symptoms, which could be a sign of another, more serious, disease.

- You lose a lot of weight for no reason.
- You have problems or pain when swallowing.
- You get stomach pain or signs of indigestion such as nausea, fullness, bloating especially after food intake.
- You begin to vomit food or blood, which may appear as dark coffee grounds in your vomit.
- You pass black stools (blood-stained faeces).
- You have severe or persistent diarrhoea; esomeprazole has been associated in the past with a small increased risk of infectious diarrhoea.
- 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 Esoprim Control. Remember to also mention any other ill-effects like pain in your joints.

Seek urgent medical attention if you experience chest pain with light-headedness, sweating, dizziness or shoulder pain with shortness of breath. This could be a sign of a serious condition with your heart.

If any of the above apply to you (or you are not sure), talk to your doctor straight away.

Children and adolescents

This medicine should not be used by children and adolescents under 18 years of age.

Drug interactions

! If you are taking, or have recently taken other medicines, including non-prescription medications or dietary supplements, tell your doctor or pharmacist.

This is because this medicine can affect the way some medicines work and some medicines can have an effect on it.

Do not take this medicine if you are also taking a medicine containing nelfinavir (used to treat HIV infection).

You should specifically tell your doctor or pharmacist if you are taking clopidogrel (used to prevent blood clots).

Do not take this medicine with other medicines that limit the amount of acid produced in your stomach such as proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole or omeprazole) or an H₂ antagonist (e.g. ranitidine or famotidine).

You may take this medicine with antacids (e.g. magaldrate, alginic acid, sodium bicarbonate, aluminium hydroxide, magnesium carbonate or combinations of these) if needed.

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

- Ketoconazole and itraconazole (used to treat infections caused by a fungus).
- Voriconazole (used to treat infections caused by a fungus) and clarithromycin (used to treat infections). Your doctor may adjust your dose of Esoprim Control if you also have severe liver problems and are treated for a long period of time.
- Erlotinib (used to treat cancer).
- Methotrexate (used to treat cancer and rheumatic disorders).
- Digoxin (used for heart problems).
- Atazanavir, saquinavir (used to treat HIV infection).
- Citalopram, imipramine or clomipramine (used to treat depression).
- Diazepam (used to treat anxiety, relax muscles or in epilepsy).
- Phenytoin (used to treat epilepsy).
- Medicines that are used to thin your blood, such as warfarin. Your doctor may need to monitor you when you start or stop taking Esoprim Control.
- Cilostazol (used to treat intermittent claudication – a condition where poor blood supply to the leg muscles causes pain and difficulty in walking).
- Cisapride (used for indigestion and heartburn).
- Rifampicin (used to treat tuberculosis).
- Tacrolimus (in cases of organ transplantation).
- St. John's wort (*Hypericum perforatum*) (used to treat depression).

! Use of this medicine and food

- You can take your capsule at any time of the day either with food or on an empty stomach.

! Pregnancy, breast-feeding and fertility.

As a precautionary measure, you should preferably avoid the use of Esoprim Control during pregnancy. You should not use this medicine during breast-feeding.

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.

! Driving and use of machinery

Esoprim Control has a low likelihood of affecting your ability to drive or use machines. However, side effects such as dizziness and visual disturbances may uncommonly occur (see section 4). If affected, you should not drive or use machines.

! Important information about some of the ingredients of this medicine

Esoprim Control contains sucrose. Esoprim Control 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, contact your doctor before taking this medicine.

3. How to use this medicine?

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure About the dosage or how to handle the medicine.

- The recommended dose is usually one capsule a day.
- **Do not exceed the recommended dose** of one capsule (20 mg) a day, even if you don't feel an improvement immediately.
- You may need to take the capsules for 2 or 3 days in a row before your reflux symptoms (for example, heartburn and acid regurgitation) get better.
- The treatment length is up to 14 days.
- When your reflux symptoms have completely gone you should stop taking this medicine.
- If your reflux symptoms get worse or do not improve after taking this medicine for 14 days in a row, you should consult a doctor.

If you have persistent or longstanding, frequently recurring symptoms even after treatment with this medicine, you should contact your doctor.

Method of administration

- Swallow your capsule whole with half a glass of water. Do not chew, crush or open the capsule. This is because the capsule contains coated pellets, which stop the medicine from being broken down by the acid in your stomach. It is important not to damage the pellets.

If you have accidentally taken a higher dosage, If you have accidentally taken an overdose or if a child has accidentally swallowed this medicine, refer to a doctor or hospital emergency room immediately and bring the package of the medicine with you. The symptoms can include diarrhoea, stomach ache, constipation, feeling or being sick and weakness.

If you forget to take the medicine

If you forget to take a dose, take it as soon as you remember it, on the same day. Do not take a double dose to make up for a forgotten dose.

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

If you have any further questions about the use of this medicine, consult a doctor or pharmacist.

4. Side effects

Like all medicines, use of Esoprim Control can cause side effects in some users. Do not be alarmed by the list of side effects; you may not suffer from any of them.

If you notice any of the following serious side effects, stop taking Esoprim Control and contact a doctor immediately:

Sudden wheezing, swelling of your lips, tongue and throat, rash, fainting, or difficulties in swallowing (severe allergic reaction, seen rarely).

- 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', seen very rarely.
- Yellow skin, dark urine and tiredness, which can be symptoms of liver problems, seen rarely.

Talk to your doctor as soon as possible if you experience any of the following signs of infection: This medicine 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 medicine at this time.

Other side effects include:

Common (may affect up to 1 in 10 people)

- Headache.
- Digestive system: diarrhoea, stomach ache, constipation, wind (flatulence).
- Feeling sick (nausea) or being sick (vomiting).
- Benign growths (polyps) in the stomach.

Uncommon (may affect up to 1 in 100 people)

- Swelling of the feet and ankles.
- Disturbed sleep (insomnia), feeling sleepy.
- Dizziness, tingling feelings such as "pins and needles".
- Spinning feeling (vertigo).
- Dry mouth.
- Increased liver enzymes shown in blood tests that check how the liver is working.
- Skin rash, lumpy rash (hives), and itchy skin.

Rare (may affect up to 1 in 1,000 people)

- Blood problems such as a reduced number of white blood 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 on the inside of the mouth.

- An infection called “thrush” which can affect the gut and is caused by a fungus.
- Hair loss (alopecia).
- Skin rash on exposure to sunshine.
- Joint pain (arthralgia), or muscle pain (myalgia).
- Generally feeling unwell and lacking energy.
- Increased sweating.

Very rare (may affect up to 1 in 10,000 people)

- Low numbers of red blood cells, white blood cells, and platelets (a condition called pancytopenia).
- Aggression.
- Seeing, feeling, or hearing things that are not there (hallucinations).
- Severe liver problems leading to liver failure and inflammation of the brain.
- Muscle weakness.
- Severe kidney problems.
- Enlarged breasts in men.

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

- Low levels of magnesium in the blood. This may cause weakness, being sick (vomiting), cramps, tremor, and changes in heart rhythm (arrhythmias). If you have very low levels of magnesium, you may also have low levels of calcium and/or potassium in your blood.
- Inflammation of the gut (leading to diarrhoea).
- Rash, possibly with pain in the joints.

If a side effect appears, if one of the side effect worsens or if you suffer from any side effect not listed in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by clicking on the link “Reporting Side Effects of Drug Treatment” found on the Ministry of Health home page (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the following link:

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

5. How to store the medicine

Avoid poisoning! This medicine, and all other medicines, must be stored in a closed place, out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use this 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

Do not store above 25°C.

Keep this medicine in the original package 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 you no longer use. These measures will help

protect the environment.

6. Additional information

What Esoprim Control contains

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, glycerol monostearate, titanium dioxide, polysorbate 80 (see section 2, "Esoprim Control contains sucrose").

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 Control 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 Control is available in a pack size of 7 or 14 gastro-resistant hard capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

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