

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

This medicine is dispensed with a doctor's prescription only

ESOMEPRAZOLE INOVAMED 20 mg

Gastro-resistant tablets

Active ingredient

Each tablet contains:

Esomeprazole 20 mg (as magnesium trihydrate)

ESOMEPRAZOLE INOVAMED 40 mg

Gastro-resistant tablets

Active ingredient

Each tablet contains:

Esomeprazole 40 mg (as magnesium trihydrate)

For the list of inactive and allergenic ingredients in this preparation, see section 6 "Further information" and section 2 "Important information about some of the ingredients in this medicine".

Read this leaflet carefully in its entirety before using the medicine.

Keep this leaflet; you may need to read it again.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

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

1. WHAT IS THE MEDICINE INTENDED FOR?

For adults, Esomeprazole Inovamed 20 mg and 40 mg are intended:

- For treatment of heartburn, with or without inflammation of the gullet, caused by reflux of acid from the stomach. Esomeprazole Inovamed reduces the production of acid and helps heal the gullet by reducing pain and inflammation.
- For treatment of ulcers in the upper part of the gut or stomach caused by *Helicobacter pylori* bacteria. Esomeprazole Inovamed, in combination with suitable antibiotics, treats the infection and leads to healing of the ulcer and prevention of recurrence.
- For healing of a gastric ulcer caused by use of nonsteroidal anti-inflammatory drugs (NSAIDs), which are also used to treat arthritis (rheumatism).
- For prevention of formation of gastric ulcers, if you may develop them due to use of nonsteroidal anti-inflammatory drugs (NSAIDs), which are also used to treat arthritis (rheumatism).
- For prolonged treatment with Esomeprazole Inovamed tablets to prevent recurrent bleeding of a gastric or duodenal ulcer, after primary intravenous esomeprazole treatment.

In adolescents, Esomeprazole Inovamed 20 mg is intended:

- For treatment of heartburn, with or without inflammation of the gullet, caused by reflux of acid from the stomach. Esomeprazole Inovamed reduces the production of acid and helps heal the gullet by reducing pain and inflammation.
- For treatment of ulcers in the upper part of the gut or stomach caused by *Helicobacter pylori* bacteria. Esomeprazole Inovamed, in combination with suitable antibiotics, treats the infection and leads to healing of the ulcer and prevention of recurrence.

In adolescents, Esomeprazole Inovamed 40 mg is intended:

- For treatment of heartburn, with inflammation of the gullet, caused by reflux of acid from the stomach. Esomeprazole Inovamed reduces the production of acid and helps heal the gullet by reducing pain and inflammation.

Therapeutic group

Proton pump inhibitors (PPI) (the gastric acid pump).

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You have a known sensitivity to any of its ingredients (listed in section 6 "Further information" and in section 2 "Important information about some of the ingredients in this medicine").
- You are sensitive (allergic) to another preparation of the proton pump inhibitors group (e.g., pantoprazole, lansoprazole, rabeprazole, omeprazole).
- You are taking a preparation that contains nelfinavir (to treat HIV infection).

Special warnings regarding use of the medicine

Before treatment with Esomeprazole Inovamed, tell the doctor if:

- You have severe liver problems.
- You have severe kidney dysfunction.
- You have ever had a skin reaction after treatment with a medicine similar to Esomeprazole Inovamed that reduces gastric acidity.
- You are due to undergo a certain blood test (chromogranin A).

Esomeprazole Inovamed may mask the symptoms of other diseases. **Therefore, if any of the following occur to you before beginning or during treatment with Esomeprazole Inovamed, refer to a doctor immediately:**

- You are suffering from unexplained weight loss and you have difficulty swallowing
- You are suffering from abdominal pain or from indigestion
- You are vomiting food or blood
- You have black stools (bloody stools)

If you are taking the medicine on-demand (according to the doctor's instructions), contact your doctor if your symptoms continue or change in any way.

Taking a proton pump inhibitor like Esomeprazole Inovamed, especially over a period of more than one year, slightly increases your risk of fractures in the bones of the hip, wrist or spine. Please inform the doctor if you have osteoporosis (bone depletion) or if you are taking corticosteroids (which can increase the risk of osteoporosis).

Rash and skin symptoms

If you get a rash on your skin, especially in areas exposed to the sun, please report to the doctor as soon as possible, as you may need to stop your treatment with Esomeprazole Inovamed. If you experience any other disease symptoms, such as joint pains, please also report them to the doctor.

Serious skin rashes have occurred in patients taking the medicine (see section 4). The rash can involve ulcers of the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). These serious skin rashes usually occur after flu-like symptoms such as fever, headaches, and body aches. The rash may cover large parts of the body with blistering and peeling of the skin. If you develop a rash or any of these skin symptoms during the treatment (even after several weeks), stop taking this medicine and contact the doctor immediately.

Children and adolescents

Esomeprazole Inovamed is not intended for use in children under the age of 12 years.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Do not take Esomeprazole Inovamed if you are being treated with a preparation that contains nelfinavir (a medicine to treat HIV infection).

Tell the doctor or the pharmacist if you are taking:

- Atazanavir (to treat HIV infection)
- Ketoconazole, itraconazole or voriconazole (to treat fungal infections).
- Citalopram, imipramine or clomipramine (to treat depression)
- Erlotinib (to treat cancer)
- Diazepam (to treat anxiety, relax muscles or in epilepsy)
- Phenytoin (for epilepsy). If you are taking phenytoin, your doctor will need to monitor you when you start or stop treatment with Esomeprazole Inovamed.
- Medicines to thin your blood, such as warfarin. Your doctor may need to monitor you when you start or stop treatment with Esomeprazole Inovamed.
- Clopidogrel (a medicine used to prevent blood clots)
- Digoxin (for heart problems).
- Rifampicin (to treat tuberculosis).
- St. John's wort (Hypericum perforatum) (to treat depression).
- Cilostazol (to treat intermittent claudication – a pain in your legs when you walk which is caused by an insufficient blood supply)
- Methotrexate (a chemotherapy medicine used at a high dosage to treat cancer); if you are taking a high dosage of methotrexate, your doctor may instruct you to temporarily stop treatment with Esomeprazole Inovamed
- Tacrolimus (after organ transplantation).
- Cisapride (to treat indigestion and heartburn)

If you are receiving Esomeprazole Inovamed together with clarithromycin and amoxicillin (antibiotics) to treat an ulcer caused by *Helicobacter pylori* bacteria, it is very important that you tell the doctor of any other medicine you are taking.

This medicine may affect the absorption of vitamin B12 in the body, especially if you need to take it for a long time. Contact your doctor if you notice any of the following symptoms, which could indicate a low level of vitamin B12:

- Extreme tiredness or lack of energy
- Paresthesia (pins and needles)
- Sore or red tongue, mouth ulcers
- Muscle weakness
- Vision disturbances
- Problems with memory, confusion, depression

Use of the medicine and food

The tablet can be taken with food or on an empty stomach.

Pregnancy, breastfeeding and fertility

If you are pregnant, think you are pregnant or are planning to become pregnant, consult the doctor or pharmacist before taking this medicine. The doctor will decide if you can take this medicine during this period.

It is not known whether esomeprazole passes into breast milk. Therefore, do not use Esomeprazole Inovamed if you are breastfeeding.

Driving and operating machinery

Esomeprazole Inovamed should not affect the ability to drive or operate machinery. However, side effects such as dizziness or blurred vision may uncommonly or rarely occur (see section 4). If you are suffering from these side effects, do not drive and do not operate machinery.

Important information about some of the ingredients in this medicine

The tablets contain sucrose (a certain type of sugar). If you have been told by the doctor that you have an intolerance to certain sugars, consult the doctor before taking this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

- If you are taking the medicine for a long time (especially if it is for more than one year), the doctor may want to perform specific monitoring.
- If your doctor has told you to take this medicine as and when you need it, tell your doctor if your symptoms change.

The doctor will tell you about taking the medicine (how many tablets and when to take them). The strength of the tablet and duration of treatment are determined by the doctor depending on your illness, your age and liver function.

The recommended dose is usually:

Use in adults aged 18 and above

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

- If your doctor has found that your gullet has been slightly damaged, the recommended dosage is one Esomeprazole Inovamed 40 mg tablet once a day for 4 weeks. The doctor may tell you to take the same dosage for a further 4 weeks if your gullet has not yet healed.
- The recommended dosage once the gullet has healed is one Esomeprazole Inovamed 20 mg tablet once a day.
- If your gullet has not been damaged, the recommended dosage is one Esomeprazole Inovamed 20 mg tablet each day. Once the illness has been controlled, the doctor may tell you to take your medicine as and when you need it, up to a maximum of one Esomeprazole Inovamed 20 mg tablet each day.
- If you have severe liver problems, your doctor may give you a lower dosage.

To treat ulcers caused by *Helicobacter pylori* infection and to stop them coming back:

- The recommended dosage is one Esomeprazole Inovamed 20 mg 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 dosage is one Esomeprazole Inovamed 20 mg 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 dosage is one Esomeprazole Inovamed 20 mg tablet once a day.

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

- The recommended dosage is one Esomeprazole Inovamed 40 mg tablet once a day for 4 weeks.

Use in adolescents aged 12 and above

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

- If your doctor has found that your gullet has been slightly damaged, the recommended dosage is one Esomeprazole Inovamed 40 mg tablet once a day for 4 weeks. The doctor may tell you to take the same dosage for a further 4 weeks if your gullet has not yet healed.
- The recommended dosage once the gullet has healed is one Esomeprazole Inovamed 20 mg tablet once a day.
- If your gullet has not been damaged, the recommended dosage is one Esomeprazole Inovamed 20 mg tablet each day.
- If you have severe liver problems, your doctor may give you a lower dosage.

To treat ulcers caused by *Helicobacter pylori* infection and to stop them coming back:

- The recommended dosage is one Esomeprazole Inovamed 20 mg tablet twice a day for one week.
- The doctor will also tell you to take antibiotics, for example amoxicillin and clarithromycin.

Instructions for use

- The tablet can be taken at any time during the day.
- The tablet can be taken with food or on an empty stomach.
- Swallow the tablet whole, with a glass of water. Do not chew or crush the tablet. This is because the tablet contains coated pellets to prevent breakdown of the medicine by the gastric acid. It is important not to damage the pellets.

The medicine is not intended for use through a feeding tube.

Do not exceed the recommended dose.

Elderly

Dose adjustment is not required in the elderly.

If you accidentally took a higher dosage or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you forgot to take this medicine at the scheduled time, take a dose as soon as you remember. However, if you remembered close to the time for the next dose, do not take the forgotten dose; take the next dose at the scheduled time.

Adhere to the treatment as recommended by the doctor.

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

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

4. SIDE EFFECTS

As with any medicine, use of Esomeprazole Inovamed may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Side effects requiring special attention:

Stop treatment and refer to a doctor immediately in the following situations:

- Yellowing of the 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 users.
- Sudden appearance of a severe rash or reddening of the skin with blisters or peeling may occur even after several weeks of treatment. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose, and genitals. The skin rashes may develop into serious widespread skin damage (peeling of the epidermis and superficial mucous membranes) with life-threatening consequences. This could be erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, or drug reaction with eosinophilia and systemic symptoms. These effects are very rare and may affect up to 1 in 10,000 users.
- Sudden wheezing, swelling of the lips, tongue and throat or body, rash, fainting or difficulties in swallowing – these are signs of a severe allergic reaction. These effects are rare and may affect up to 1 in 1,000 users.

Additional side effects

Common side effects, effects that occur in 1-10 in 100 users:

- headache
- effects on the stomach or gut: diarrhea, stomach pain, constipation, flatulence
- nausea and vomiting
- benign polyps in the stomach

Uncommon side effects, effects that occur in 1-10 in 1,000 users:

- swelling of the legs and ankles
- sleep problems (insomnia)
- dizziness, tingling feelings ("pins and needles"), sleepiness
- spinning feeling (vertigo)
- dry mouth
- changes in liver function blood tests
- skin rash, lumpy rash (hives) and itchy the skin
- fracture of the hip, wrist or spine (when using Esomeprazole Inovamed at a high dosage for a long time)

Rare side effects, effects that occur in 1-10 in 10,00 users:

- 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
- eyesight problems such as blurred vision
- sudden wheezing or shortness of breath (bronchospasm)
- inflammation of the inside of the mouth
- a fungal infection called thrush 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 pains or muscle pains
- feeling unwell and lack of energy
- excessive sweating

Very rare side effects, effects that occur in less than one user in 10,000:

- sudden onset of a severe rash, skin blistering or peeling. This may be accompanied by high fever and joint pains (erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms)
- changes in blood count, including agranulocytosis (reduction in white blood cells)
- aggression
- seeing, feeling or hearing things that do not exist (hallucinations)
- severe liver problems that lead to liver failure and inflammation of the brain
- muscle weakness
- severe kidney problems
- enlarged breasts in men

Side effects of unknown frequency (side effects whose frequency has not yet been established):

- low magnesium levels in the body: If you are taking Esomeprazole Inovamed for more than three months, the magnesium levels in your blood may decline. Symptoms that may indicate reduced magnesium levels include: fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness or increased heart rate. Please inform the doctor immediately if you experience any of these symptoms. Low levels of magnesium may also lead to reduced potassium or calcium levels in the blood. The doctor may decide to perform blood tests regularly to monitor your magnesium levels.
- inflammation in the gut (which causes diarrhea)
- rash, usually with joint pains

In very rare cases, Esomeprazole Inovamed may affect the white blood cells and lead to immune deficiency. If you have an infection with symptoms such as fever with a **severe** decline in your general condition or fever with symptoms of a local infection such as pain in the neck, throat or mouth or difficulties passing water, consult the doctor as soon as possible to rule out the possibility of lack of white blood cells (agranulocytosis), by a blood test. You must tell the doctor that you are using Esomeprazole Inovamed.

If a side effect occurs, if one of the side effects worsens or if you are suffering from a side effect not mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking on the "Reporting side effects of drug treatment" link on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning!** This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor!
- Store this medicine below 25°C.
- Store in the original package to protect from moisture.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION

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

Microcrystalline cellulose, methacrylic acid ethyl acrylate copolymer (1:1) dispersion 30 percent (eudragit L30-D55), sugar spheres (non-pareil seeds 40-50 mesh), hypromellose phthalate, confectioner's sugar (icing sugar with starch), macrogol 6000, macrogol 400, crospovidone XL, colloidal hydrated silica, hydroxypropylcellulose, starch pregelatinized, povidone, magnesium oxide light, glycerol monostearate 40-55, talc, polysorbate 80, ferric oxide red.

Esomeprazole Inovamed 20 mg also contains:

Opadry pink 03B84893: HPMC 2910/Hypromellose 6cP, titanium dioxide, macrogol/PEG 400, iron oxide red, iron oxide yellow.

Esomeprazole Inovamed 40 mg also contains:

Opadry pink 03B54193: HPMC 2910/Hypromellose 6cP, titanium dioxide, macrogol/PEG 400, iron oxide red.

What the medicine looks like and the contents of the package:

Esomeprazole Inovamed 20 mg – an oblong, light pink-colored, biconvex, coated tablet, debossed with '20' on one side and 'CE' on the other side.

Esomeprazole Inovamed 40 mg – an oblong, pink-colored, biconvex, coated tablet, debossed with '40' on one side and 'CE' on the other side.

Package sizes: 7, 14, 28, 30, 50, 56 or 60 tablets. Not all package sizes may be marketed.

Registration holder and importer: Inovamed Ltd., P.O.B. 62, Even Yehuda, 40500.

Manufacturer: Jubilant Generics Ltd., 1-A sector 16-A, Noida, Uttar Pradesh 201301, India.

Revised in October 2023 in accordance with the Ministry of Health guidelines.

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

Esomeprazole Inovamed 20 mg: 161-48-35207

Esomeprazole Inovamed 40 mg: 161-49-35208