

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

Composition

Each tablet contains:

Esomeprazole 20 mg (as magnesium trihydrate)

ESOMEPRAZOLE INOVAMED 40 mg

Gastro-resistant tablets

Composition

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.

Treatment of ulcers in the upper 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.

Healing of gastric ulcer caused by use of nonsteroidal anti-inflammatory drugs (NSAIDs), such as preparations to treat arthritis.

Prevention of formation of gastric ulcers, if you may develop them due to use of NSAIDs, such as preparations to treat arthritis.

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 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").
- You have a known sensitivity to another preparation of the proton pump inhibitors group (preparations to treat ulcer-like symptoms, e.g., pantoprazole, lansoprazole, rabeprazole, omeprazole).
- You are being treated with a preparation that contains nelfinavir (a medicine to treat immune deficiency syndrome (HIV)).

Special warnings regarding use of the medicine

Before beginning treatment with Esomeprazole Inovamed, tell the doctor if:

- You are suffering, or have suffered in the past, from severe liver function impairment.
- You are suffering, or have suffered in the past, from severe kidney function impairment.
- You suffered in the past from a skin reaction after treatment with a medicine similar to Esomeprazole Inovamed that lowers 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 or 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 this medicine when needed (as per the doctor's instructions), please inform the attending doctor. You must also tell the attending doctor if there is any change in your symptoms. There is an increased risk of broken bones in the hip, wrist and back upon prolonged use of Proton pump inhibitors (PPI) for one year or more. Please inform the doctor if you have been diagnosed with osteoporosis (bone thinning – patients with this disease are more prone to fractures) or if you are taking corticosteroids.

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 quickly as possible, as you may need to stop your treatment with Esomeprazole Inovamed. If you experience any other symptoms, such as joint pains, please report them also to the doctor.

Serious 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.

Drug interactions

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

Do not take Esomeprazole Inovamed if you are taking a preparation that contains nelfinavir (a medicine to treat immune deficiency syndrome (HIV)).

Tell the doctor or pharmacist if you are taking:

- Atazanavir (to treat immune deficiency syndrome - HIV)
- Medicines to treat fungal infection (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 at the beginning and end of Esomeprazole Inovamed treatment.
- Blood thinners (warfarin) – the doctor will have to monitor the treatment at the beginning and end of Esomeprazole Inovamed treatment.
- Clopidogrel (a medicine used to prevent blood clots)
- Medicines for heart problems (digoxin)
- If you are taking medicinal treatment for tuberculosis (rifampicin)
- A preparation for treatment of depression: St John's wort (*Hypericum perforatum*)
- Medicines intended to treat arterial diseases in the legs that cause intermittent limping (cilostazol)
- Methotrexate (a medicine used at a high dosage to treat cancer). If you are taking a high dosage of methotrexate, the doctor may tell you to temporarily stop treatment with Esomeprazole Inovamed.
- A medicine to treat transplant rejection after an organ transplant (tacrolimus)
- Medicines to accelerate gastric emptying (cisapride) in combined treatment with Esomeprazole Inovamed.

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

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 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 shouldn't affect the ability to drive or operate machinery. However, side effects such as dizziness or blurred vision may occur. 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. The doctor will explain to you how to take the medicine (how many tablets and when to take). The strength of the tablet and duration of treatment are determined by the doctor in accordance with the disease from which you are suffering.

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 certain tests. If the doctor has told you to take the medicine as needed, tell the doctor if the symptoms change.

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 medicine whole, with half a glass of water. Do not chew or crush the parts of the tablet. The tablet contains coated pellets to prevent breakdown of the medicine by the gastric acid and it is therefore important not to crush the particles.

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

Elderly patients

The dosage does not have to be adjusted for elderly patients.

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.

How can you contribute to the success of the treatment?

Adhere to the treatment regimen recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Care should be taken to implement the dosing instructions accurately and ask the doctor in case of any doubt.

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 can be symptoms of liver problems. These effects are rare and may affect up to 1 in 1,000 people.
- sudden onset of a severe rash or skin redness 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 widespread skin damage (peeling of the epidermis and superficial mucous membranes) with life threatening consequences. These could be erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis or drug reaction with eosinophilia and systemic symptoms. These effects are rare, and might affect up to 1 in 1,000 people.
- 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.

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

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

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 itching of 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 (bronchoconstriction)
- an inflammation inside the mouth
- a fungal infection that may affect the intestine
- 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
- muscle pains
- malaise 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 (multiforme erythema, 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 leading 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 been established yet):

- 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: involuntary muscle contractions, disorientation, seizures, dizziness or increased heart rate. Please inform the doctor immediately if you experience these symptoms. Low levels of magnesium may also lead to reduced potassium or calcium levels in your blood.
- The doctor may decide to regularly perform blood tests 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 general condition or fever with signs of a local infection such as pain in the neck, throat or mouth or difficulties passing water, consult the doctor immediately to rule out the possibility of lack of white blood cells (agranulocytosis) by a blood test. You should 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. In any case of doubt, consult the pharmacist who dispensed the medicine to you.

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., 55 Be'er Ganim St., P.O.B. 62, Even Yehuda, 40500.

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

Revised in July 2022 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