

The format of this leaflet was determined by the Health Ministry, which examined and approved its content on January 2019

Consumer Leaflet According to Pharmacists Regulations (Preparations), 1986

This medicine is dispensed with a doctor's prescription only

Esomeprazole Inovamed 20 mg Gastro Resistant Tablets	Esomeprazole Inovamed 40 mg Gastro Resistant Tablets
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Composition

Each tablet contains: Esomeprazole 20 mg (as magnesium amorphous)	Each tablet contains: Esomeprazole 40 mg (as magnesium amorphous)
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For the list of inactive and allergenic ingredients in the preparation, see section 6- "Additional information" and section 2-" Important Information on Some of the ingredients of the medicine".

Read the entire leaflet carefully before using the medicine.

Keep the leaflet – You may need it again.
This leaflet contains concise information on the medicine. If you have additional questions, contact the doctor or the pharmacist.
This medicine was recorded for treating your illness. Do not pass it to others. It may harm them even if they appear to have an illness similar to yours.

1. What is the medicine intended for? In adults, Esomeprazole Inovamed 20 mg and 40 mg are intended for:

For the treatment of heartburn with or without inflammation of the esophagus, which is the result of reflux of stomach acids.

Esomeprazole Inovamed reduces the production of acid and assists in the healing of the esophagus by reducing pain and inflammation. Treatment of ulcers in the upper part of the intestine or the stomach, which are caused by the *Helicobacter Pylori* bacteria. Esomeprazole Inovamed, in combination with the suitable antibiotics, treats the infection and causes the ulcer to heal and prevents its recurrence.

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

Preventing the formation of stomach ulcers, if you may develop them due to non-steroidal anti-inflammatory drugs, such as drugs treating arthritis (rheumatism).

Prolonged treatment with Esomeprazole Inovamed tablets to prevent recurrent bleeding of a gastric stomach or duodenal ulcer, after primary intravenous Nexium treatment.

In adolescents, Esomeprazole Inovamed 20 mg is intended for:

- For treatment of heartburn with or without inflammation of the esophagus, which is the result of reflux of stomach acids. Esomeprazole Inovamed reduces the production of acid and assists in the healing of the esophagus by reducing pain and inflammation.
- For treatment of ulcers in the upper part of the intestine or the stomach, which are caused by the *Helicobacter Pylori* bacteria. Esomeprazole Inovamed, in combination with the suitable antibiotics, treats the infection and causes the ulcer to heal and prevents its recurrence.

In adolescents, Esomeprazole Inovamed 40 mg is intended for:

- For the treatment of heartburn with or without inflammation of the esophagus, which is the result of reflux of stomach acids. Esomeprazole Inovamed reduces the production of acid and assists in the healing of the esophagus by reducing pain and inflammation.

Therapeutic Group

Proton pump inhibitor (the acid pump of the stomach).

2. Before using the medicine

❗ Do not use the medicine if:

- There is known sensitivity to one of its components (that are specified in section 6 Additional Information).
- There is a known sensitivity to another preparation of the proton pump inhibitor group (preparations to treat ulcer-like symptoms such as Pantoprazole, Lansoprazole, Rabeprazole, Omeprazole).
- You are being treated with the medicine that contains Nelfinavir (a medicine that treats acquired immunodeficiency syndrome [HIV]).

Special warnings regarding use of Esomeprazole Inovamed

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

- You suffer or have previously suffered from a severe liver dysfunction.
- You suffer or have previously suffered from a severe kidney dysfunction.
- You have previously suffered from a skin reaction after treatment with a drug similar to Esomeprazole Inovamed which reduces the stomach's acidity.
- If you are due to undergo a specific blood test (Chromogranin A).

Esomeprazole Inovamed could mask the symptoms of other illnesses. **Therefore, if one of the following occurs before starting treatment with Esomeprazole Inovamed or during treatment with Esomeprazole Inovamed, refer to the doctor immediately:**

- You suffer from an unexplained weight loss or have difficulty swallowing
- You suffer from abdominal pain or digestive difficulties
- You vomit food or blood
- You have black stools (bloody stools)

If you are taking the medicine as needed (according to the doctor's instructions), please notify the attending doctor. In addition, you must also notify the attending doctor if there is any change in your symptoms.

There is increased risk for fractures in the bones of the hip, wrist and back upon prolonged use for one year or more. Please notify the doctor if you have been diagnosed with osteoporosis (bone depletion – those having disease are more prone to fractures) or if you are taking corticosteroids.

- If you have a rash on your skin, particularly in areas that are exposed to the sun, please tell the doctor as soon as possible since you may need to stop treatment with Esomeprazole Inovamed. If you experience additional disease symptoms, such as joint pains, please report to the doctor as well.

⚠ If you are taking other medicines

Please tell the attending doctor if you are taking other medicines or if you have just finished treatment with another medication, including non-prescription medicines and herbal medicines. This is because Esomeprazole Inovamed may affect the way certain medicines work, or certain medicines may affect the way Esomeprazole Inovamed works.

- Do not take Esomeprazole Inovamed if you are taking medicine contains Nelfinavir (a medicine that

treats acquired immunodeficiency syndrome [HIV]).

Tell the doctor or pharmacist if you are taking:

- Atazanavir (for treating acquired immunodeficiency syndrome – HIV).
- Medicines for treating a fungal infection (Ketoconazole, Itraconazole and Voriconazole).
- Antidepressant drugs (Citalopram, Imipramine and 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), your doctor will have to monitor your 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 medicine for Tuberculosis (Rifampicin).
- Medicines for treating depression: St. John's wort (*Hypericum perforatum*).
- Medicines intended for treating arterial diseases in the legs, which cause an impermanent claudication (Cilostazol).
- Methotrexate (a medicine used to treat cancer at a high dosage), if you are taking a high dosage of Methotrexate, the doctor may instruct you to temporarily cease treatment with Esomeprazole Inovamed;
- A Medicine for treating transplant rejection after an organ transplant (Tacrolimus).
- Certain medicines for treating malignant tumors (such as Erlotinib).
- Medicines to accelerate gastric emptying (Cisapride) in combined treatment with Esomeprazole Inovamed;

If you are receiving Esomeprazole Inovamed together with Clarithromycin and Amoxicillin to treat an ulcer caused by the *Helicobacter Pylori* bacteria, it is important that you tell your doctor about any additional medicine you are taking.

⚠ Use of Esomeprazole Inovamed and Food

You can take the tablet with food or on an empty stomach.

⚠ Pregnancy and Breastfeeding

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

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

⚠ Driving and Operating Machinery

Esomeprazole Inovamed is not supposed to affect your ability to drive or operate machinery. However, side effects such as dizziness or blurry vision may occur. If you are suffering from these side effects, do not drive or operate machinery.

⚠ Important Information on Some of the ingredients of the medicine

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

3. How to use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or the pharmacist if you are not sure.

The doctor will tell you about taking the medicine (how many tablets and when to take). The strength of the tablet and duration of the treatment are determined by the doctor in accordance with the disease from which you are suffering.

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

If the doctor told you to take the medicine as needed, tell your doctor if your 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 the breakdown of the medicine by the gastric acid and it is therefore important not to crush the pellets.

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

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 contact 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 designated 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 designated time.

How can you contribute to the success of treatment?

You must complete the treatment as recommended by the doctor.

Even if there has been an improvement in your health, do not stop treatment with the medicine without consulting the doctor. Be sure to accurately implement the instructions for taking the medicine and to ask the doctor if there is any doubt.

4. Side Effects

As with any medicine, use of Esomeprazole Inovamed may cause side effects with some users. Do not be alarmed when reading the list of side effects. It is possible you may not suffer from any of them.

Side effects that require special attention:

Cease treatment and contact a doctor immediately in the following cases:

- Sudden wheezing when breathing, shortness of breath, swelling of the lips, tongue and throat or the body, rash, fainting or difficulties swallowing – these are signs of a severe allergic reaction.
- Reddening in the skin with blisters or peeling. Blisters and bleeding may also appear on the lips, eyes, mouth, nose and genitals. This may be Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis.
- Yellowing of the skin and sclera, dark urine and fatigue maybe symptoms of liver problems.

These effects are rare may affect less than 1 in 1,000 people.

Common side effects, effects that appear in 1-10 users out of 100:

- Headache
- Diarrhea, stomach ache, constipation, - flatulence
- Nausea and vomiting

Uncommon side effects, effects that appear in 1-10 users out of 1,000:

- Swelling of the legs and ankles
- Sleeping Problems (insomnia)
- Dizziness, a tingling feelings ("pins and needles")
- Sleepiness

- Spinning feelings (vertigo)
- Dry mouth
- Changes in liver functions blood tests
- Rash, blisters on and itching of the skin
- Fractures of the hip, wrist or spine (when using Esomeprazole Inovamed at a high dosage for a long time)
- An increase in liver enzymes

Rare side effects, effects that appear in 1-10 users out of 10,000:

- Blood problems such as a reduced number of white cells or platelets – can cause weakness, bruising or increased risk of infection.
- 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 (construction of the windpipe).
- Mouth infection;
- A fungal infection that may impact the gut;
- Liver problems, including jaundice which may cause a yellowing of the skin, dark urine and tiredness
- Hair loss.
- Skin rash on exposure to sun
- Joint pains.
- Muscle pains
- Feeling sick and lacking energy
- Hyperhidrosis

Very rare side effects, effects that appear in less than one user out of 10,000:

- Sudden onset of a severe rash, blisters or peeling of the skin. This may be accompanied by a high fever and joint pains, (Erythema multiforme, Stevens-Johnson syndrome, Toxic Epidermal Necrolysis)
- Changes in blood counts, agranulocytosis (reduction in white blood cells)
- Aggression
- Hallucinations
- Severe liver problems, leading to liver failure and encephalitis
- Muscle weakness
- Severe kidney problems
- Enlarged breasts in men

Side effects whose prevalence is unknown (effects whose prevalence has to be determined):

- Low levels of magnesium in the body: this problem could be severe. Low levels of magnesium in the body may occur in certain people who took medical preparations from the proton pump inhibitor group (gastric acid pump) such as Esomeprazole Inovamed, for at least three months. If the magnesium levels drop, symptoms of low levels of magnesium may occur.

Please notify your doctor immediately if you experience the following symptoms:

- Dizziness
 - Disorientation
 - Fatigue
 - Convulsions
 - Increased heart rate
 - Involuntary muscle cramps
 - Low blood magnesium level can cause low blood calcium and/or low blood potassium levels
- If you are required to take Esomeprazole Inovamed for a long time, your doctor may check the magnesium levels in your body before or during treatment with Esomeprazole Inovamed.
- Enteritis (that causes diarrhea).
 - A rash, usually in combination 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 overall wellbeing or a fever with symptoms of a local infection such as pains in the head and neck, throat or mouth or difficulties urinating, consult with a doctor immediately in order to rule out the possibility of lack of white blood cells (Agranulocytosis) by blood test. You must inform the doctor that you are using Esomeprazole Inovamed.

If a side effect has appeared, if one of the side effects worsens, or when you suffer from a side effect that was not mentioned in the leaflet, consult with the doctor.

You can report side effects to the Ministry of Health by clicking the "report side effects due to drug treatment" link on the home page of the Ministry of Health website (www.health.gov.il), which refers you to an online form for reporting side effects , or by entering the link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a close place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor!
- Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.
- This medicine must be kept in a cool and dry place.
- Do not store this medicine in the temperature that exceeds 25° C.
- Please store in the original package in order to protect it against humidity. Do not use the medicine after the expiry date appearing on the package. The expiry date refers to the last day of that month. In any case of doubt, consult the pharmacist who provided you with the medicine.
- Do not store different medicines in the same package.

6. Additional Information

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

Esomeprazole Inovamed 20 mg:

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 (ling sugar with starch), opadry pink 03B84893, macrogol 400, macrogol 6000, crospovidone, lactose monohydrate, silica (colloidal hydrated), hydroxypropylcellulose, starch pregelatinized, povidone, magnesium oxide light, glycerol monostearate 40-55, talc, polysorbate 80, ferric oxide red.

Each tablet of Esomeprazole Inovamed 20 mg contains 9.25 mg of lactose monohydrate

Each tablet of Esomeprazole Inovamed 20 mg contains 57.6 mg of sucrose

Esomeprazole Inovamed 40 mg:

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 (ling sugar with starch), opadry pink 03B54193, macrogol 400, macrogol 6000, crospovidone, lactose monohydrate, silica (colloidal hydrated), hydroxypropylcellulose, starch pregelatinized, povidone, magnesium oxide light, glycerol monostearate 40-55, talc, polysorbate 80, ferric oxide red.

Each tablet of Esomeprazole Inovamed 40 mg contains 18.5mg of lactose monohydrate

Each tablet of Esomeprazole Inovamed 40 mg contains 115.2mg of sucrose

Description of the Dosage Form:

Esomeprazole Inovamed 20 mg, Tablets: Coated tablets that are oblong, biconvex, light pink colored, debossed with '20' on one side and 'CE' on the other. Esomeprazole Inovamed 40 mg, Tablets: Coated tablets that are oblong, biconvex, pink colored, debossed with '40' on one side and 'CE' on the other.

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

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

20 mg: 161-48-35207

40 mg: 161-49-35208

Manufacturer:

Jubilant Generics Ltd., 1-A, Sector 16-A, Noida, Uttar Pradesh 201301, India.

Registration holder: Inovamed Ltd., PC 513988089, 55 Beer Ganim Street, P.O.B. 62, Even Yehuda 40500

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