

Package leaflet: information for the patient

Esomeprazole-Tchaikapharma 40 mg powder for solution for injection/infusion

(esomeprazole)

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Esomeprazole-Tchaikapharma is and what it is used

Esomeprazole-Tchaikapharma contains a medicine called esomeprazole. This belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces.

Esomeprazole-Tchaikapharma is used for the short-term treatment of certain conditions, when you are unable to have treatment by mouth. It is used to treat the following conditions:

Adults:

- „Gastroesophageal reflux disease“ (GERD). This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn.
- Stomach ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). Esomeprazole-Tchaikapharma can also be used to stop stomach ulcers from forming if you are taking NSAIDs.
- Prevention of rebleeding following therapeutic endoscopy for acute bleeding gastric or duodenal ulcers.

Children and adolescents aged 1-18 years:

- „Gastroesophageal reflux disease“ (GERD). This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn.

2. What you need to know before you take Esomeprazole-Tchaikapharma

Do not use Esomeprazole-Tchaikapharma:

- If you are allergic to esomeprazole or any of the other ingredients of this medicine (listed in section 6);
- If you are allergic to other proton pump inhibitor medicines (e.g. pantoprazole, lansoprazole, rabeprazole, omeprazole);
- If you are taking a medicine containing nelfinavir (used to treat HIV infection).

If any of these apply to you, you should not be given Esomeprazole-Tchaikapharma. If you are not sure, talk to your doctor or nurse before you are given this medicine.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given Esomeprazole-Tchaikapharma:

- you have severe liver problems;
- you have severe kidney problems;
- You have ever had a skin reaction after treatment with a medicine similar to EsomeprazoleTchaikapharma that reduces stomach acid;
- you are due to have a specific blood test (Chromogranin A).

Esomeprazole-Tchaikapharma may hide the symptoms of other diseases. **Therefore, if any of the following happen to you before you are given Esomeprazole-Tchaikapharma or after you are given it, talk to your doctor straight away:**

- you lose a lot of weight for no reason and have problems swallowing;
- you get stomach pain or indigestion;
- you begin to vomit food or blood;
- you pass black stools (blood-stained) faeces.

Taking a proton pump inhibitor like Esomeprazole-Tchaikapharma, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

If 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 Esomeprazole-Tchaikapharma. Remember to also mention any other ill effects like pain in your joints.

When taking Esomeprazole-Tchaikapharma, inflammation in your kidney may occur. Signs and symptoms may include decreased volume of urine or blood in your urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness. You should report such signs to the treating physician.

Other medicines and Esomeprazole-Tchaikapharma

Tell your doctor or nurse if you are taking, have recently taken, or might take any other medicines. This includes medicines that you buy without a prescription. This is because esomeprazole can affect the way some medicines work and some medicines can have an effect on EsomeprazoleTchaikapharma.

You must not be given Esomeprazole-Tchaikapharma, if you are taking a medicine containing **nelfinavir** (used to treat HIV infection).

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

- atazanavir (used to treat HIV infection);
- ketoconazole, itraconazole or voriconazole (used to treat infections caused by a fungus);
- citalopram, imipramine or clomipramine (used to treat depression);
- diazepam (used to treat anxiety, relax muscles or in epilepsy);
- phenytoin (used in epilepsy). If you are taking phenytoin, your doctor will need to monitor you when you start or stop having Esomeprazole-Tchaikapharma;

- medicines that are used to thin your blood, such as warfarin, clopidogrel. Your doctor may need to monitor you when you start or stop having Esomeprazole-Tchaikapharma;
- cilostazol (used to treat intermittent claudication – a pain in your legs when you walk which is caused by an insufficient blood supply);
- tacrolimus (organ transplantation);
- cisapride (used for indigestion and heartburn);
- erlotinib (used to treat cancer);
- кларитромицин (използва се за лечение на инфекции);
- digoxin (used for heart problems);
- rifampicin (used for treatment of tuberculosis);
- St. John's wort (*Hypericum perforatum*) (used to treat depression);
- methotrexate (a chemotherapy medicine used in high doses to treat cancer) – if you are taking a high dose of methotrexate, your doctor may temporarily stop your Esomeprazole-Tchaikapharma treatment.

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you are given this medicine. Your doctor will decide whether you can take Esomeprazole-Tchaikapharma during this time.

It is not known if Esomeprazole-Tchaikapharma passes into breast milk, therefore it should not be used during breast-feeding.

Driving and using machines

Esomeprazole-Tchaikapharma is not likely to affect you being able to drive or use any tools or machines. However, side effects such as dizziness and blurred vision may uncommonly occur (see section 4). If affected, you should not drive or use machines.

Esomeprazole-Tchaikapharma contains sodium

This medicine contains less than 1 mmol sodium (23 mg) in dose, i.e. practically does not contain sodium.

3. How to take Esomeprazole-Tchaikapharma

Esomeprazole-Tchaikapharma can be given to children and adolescents aged 1-18 years and adults, including the elderly.

Being given Esomeprazole-Tchaikapharma

Adults

- Esomeprazole will be given to you by your doctor who will decide how much you need;
- The recommended dose is 20 mg or 40 mg once a day.
- If you have severe liver problems, the maximum dose is 20 mg a day (GERD).
- The medicine will be given to you as an injection or infusion into one of your veins. This will last for up to 30 minutes.
- The recommended dose for prevention of re-bleeding of gastric or duodenal ulcer, is 80 mg administered as intravenous infusion over 30 minutes followed by a continuous infusion of 8 mg/hr given over 3 days. If you have severe liver problems, a continuous infusion of 4 mg/hr given over 3 days may be sufficient.

Children aged 1 to 18 years

- Esomeprazole-Tchaikapharma will be given by your doctor who will decide how much you need;

- For children 1-11 years, the recommended dose is 10 or 20 mg given once a day;
- For children 12-18 years, the recommended dose is 20 or 40 mg given once a day;
- The medicine will be given as an injection or infusion into a vein. This will last up to 30 minutes.

If you are given more Esomeprazole-Tchaikapharma than you should

If you think you have been given too much Esomeprazole-Tchaikapharma, talk to your doctor straight away.

4. Possible side effects

Like all medicines, Esomeprazole-Tchaikapharma can cause side effects, although not everybody gets them.

If you notice any of the following serious side effects, stop taking Esomeprazole-Tchaikapharma and contact a doctor immediately:

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction).
- 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”.
- Yellow 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 people.

Other side effects include:

Common (may affect up to 1 in 10 people)

- Headache;
- Effects on your stomach or gut: diarrhoea, stomach pain, constipation, wind (flatulence);
- Feeling sick (nausea) or being sick (vomiting);
- Injection site reaction.

Uncommon (may affect up to 1 in 100 people)

- Swelling of the feet and ankles;
- Disturbed sleep (insomnia);
- Dizziness, tingling feelings such as “pins and needles”, feeling sleepy;
- Spinning feeling (vertigo);
- Eyesight problems such as blurred vision;
- Dry mouth;
- Changes in blood tests that check how the liver is working;
- Skin rash, lumpy rash (hives) and itchy skin;
- Fracture of the hip, wrist or spine (if Esomeprazole-Tchaikapharma is used in high doses and over long duration).

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

- Blood problems such as a reduced number of white 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;

- Suddenly feeling wheezy or short of breath (bronchospasm);
- An inflammation of the inside of the mouth;
- An infection called “thrush” which can affect the gut and is caused by a fungus;
- Liver problems, including jaundice which can cause yellow skin, dark urine, and tiredness;
- Hair loss (alopecia);
- Skin rash on exposure to sunshine;
- Joint pains (arthralgia) or muscle pains (myalgia);
- Generally feeling unwell and lacking energy;
- Increased sweating.

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

- Changes in blood count including agranulocytosis (lack of white blood cells);
- Aggression;
- Seeing, feeling or hearing things that are not there (hallucinations);
- Severe allergic reactions (swelling, anaphylactic reaction/shock);
- Severe liver problems leading to liver failure and inflammation of the brain;
- Sudden onset of a severe rash or blistering or peeling skin. This may be associated with a high fever and joint pains (Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis);
- Muscle weakness;
- Severe kidney problems;
- Enlarged breasts in men.

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

- Inflammation in the gut (leading to diarrhoea);
- If you are on Esomeprazole-Tchaikapharma for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness or increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium;
- Rash, possibly with pain in the joints.

Esomeprazole-Tchaikapharma 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 medication at this time.

Don't worry about this list of possible side effects. You may not receive any of them. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist or nurse.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Bulgarian Drug Agency
8 Damyan Gruev Str,
1303 Sofia, Bulgaria Tel.:
+359 2 8903417 website:
www.bda.bg

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Esomeprazole-Tchaikapharma

Keep this medicine out of the sight and reach of children.

The doctor and hospital pharmacist are responsible for storing, using and disposing of EsomeprazoleTchaikapharma correctly.

Do not use this medicine after the expiry date which is stated on the carton and vial after EXP. The expiry date refers to the last day of that month.

Do not store above 30° C.

Keep the vial in the outer carton in order to protect from light.

Destruction

Do not throw away any medicines via wastewater or household waste. Your doctor or nurse will throw away any medicine you no longer need, as well as used needles and syringes. These measures will help to protect the environment.

6. Contents of the pack and other information

What Esomeprazole-Tchaikapharma contains

- The active substance is esomeprazole sodium. Each vial of powder for solution for injection/infusion contains 42.5 mg of esomeprazole sodium, equivalent to 40 mg of esomeprazole;
- The other ingredients are: disodium edetate and sodium hydroxide (to adjust the pH).

What Esomeprazole-Tchaikapharma looks like and contents of the pack

Esomeprazole-Tchaikapharma is a white to off-white cake or powder. This is made into a solution before it is given to you.

Each pack contains 1, 5 or 10 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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The following information is intended for medical or healthcare professionals only:

Esomeprazole-Tchaikapharma 40 mg powder for solution for injection/infusion contains 40 mg esomeprazole such as sodium salt. Each vial contains and disodium edetate and sodium hydroxide (< 1 mmol sodium).

The vials are for single use only. If it is not necessary to use the entire amount of solution prepared from the contents of the vial for one dose, the unused solution should be discarded.

For more information on recommended dosages and storage conditions, see section 3 and 5.

Preparation and application of the prepared solution:

To prepare the solution, remove the colored plastic cap of the Esomeprazole-Tchaikapharma vial; pierce the stopper in the center of the defined circle, holding the needle vertically so that it can pass properly through the stopper.

Infusion solution is light yellow. Prior to administration, the reconstituted solution should be inspected visually for particulate matter and discoloration. Should be used only clear solution.

Chemical and physical in-use stability of the solution has been demonstrated for 12 hours 30° C. From a microbiological point of view, the product should be used immediately. If not used immediately, inuse storage times and conditions prior to use are the responsibility of the user and would like to store the solution for up to 24 hours at 2-8 ° C (in a refrigerator)..

Esomeprazole-Tchaikapharma injection

To prepare a solution for injection:

Injection 40 mg

For solution with concentration 8 mg/ml esomeprazole: prepare the solution by adding 5 ml of 0.9% (9 mg/ml) sodium chloride for intravenous administration to the vial of esomeprazole 40 mg.

The reconstituted solution for injection should be administered intravenously over a period of at least 3 minutes.

For further information on dose administration, please see SPC section 4.2.

Esomeprazole-Tchaikapharma infusion

To prepare a solution for infusion:

Infusion 40 mg

Dissolve the contents of one vial of esomeprazole 40 mg in 100 ml 0,9% sodium chloride for intravenous administration.

Infusion 80 mg

Dissolve the contents of two vials of esomeprazole 40 mg in up to 100 ml of 0.9% sodium chloride for intravenous administration.

For further information on dose administration, please see SPC section 4.2.

Disposal

Any unused product or waste material should be disposed of in accordance with local requirements.