Package leaflet: Information for the patient

Esomeprazole Krka 20 mg hard gastro-resistant capsules
Esomeprazole Krka 40 mg hard gastro-resistant capsules
esomeprazole

Read all of this leaflet carefully before you start taking 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Esomeprazole Krka is and what it is used for

Esomeprazole Krka contains the active substance called esomeprazole magnesium dihydrate. This belongs to a group of medicines called "proton pump inhibitors". They work by reducing the amount of acid that your stomach produces.

Esomeprazole Krka is used to treat the following conditions:

Adults
- Gastro-esophageal 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.
- Ulcers in the stomach or upper part of the gut (intestine) that are infected with bacteria called "*Helicobacter pylori*". If you have this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.
- Stomach ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). Esomeprazole Krka can also be used to stop stomach ulcers from forming if you are taking NSAIDs.
- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).
- Prolonged treatment after prevention of rebleeding of ulcers with intravenous esomeprazole.

Adolescents aged 12 years and above
- "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.
- Ulcers in the stomach or upper part of the gut (intestine) that are infected with bacteria called "*Helicobacter pylori*". If you have this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.

2. What you need to know before you take Esomeprazole Krka

Do not take Esomeprazole Krka if
- You are allergic to esomeprazole or any of the other ingredients of this medicine (listed in

section 6).
- You are allergic to other proton pump inhibitor medicines (e.g. pantoprazole, lansoprazole, rabeprazole, omeprazole).
- You are taking a medicine containing nelfinavir (used to treat HIV infection).

Do not take Esomeprazole Krka if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Esomeprazole Krka.

Warnings and precautions
Talk to your doctor or pharmacist before taking Esomeprazole Krka if:
- You have severe liver problems.
- You have severe kidney problems.
- You have vitamin B12 deficiency.
- You have ever had a skin reaction after treatment with a medicine similar to Esomeprazole Krka that reduces stomach acid.
- You are due to have a specific blood test (Chromogranin A).

Esomeprazole Krka may hide the symptoms of other diseases. **Therefore, if any of the following happen to you before you start taking Esomeprazole Krka or while you are taking 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).

If you have been prescribed Esomeprazole Krka "on demand" you should contact your doctor if your symptoms continue or change in character.

Taking a proton pump inhibitor like Esomeprazole Krka, 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).

Rash and skin symptoms
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 Krka. Remember to also mention any other ill-effects like pain in your joints.

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

Children under the age of 12 years
Esomeprazole Krka is not recommended for children less than 12 years old.

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

Do not take Esomeprazole Krka capsules if you are taking a medicine containing **nelfinavir** (used to treat HIV).

Tell your doctor or pharmacist if you are taking any of the following medicines:
- Atazanavir (used to treat HIV infection).

- Digoxin (used to treat heart problems).
- Ketoconazole, itraconazole or voriconazole (used to treat infections caused by a fungus).
- Erlotinib (used to treat cancer).
- 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 taking Esomeprazole Krka.
- Medicines that are used to thin your blood, such as warfarin. Your doctor may need to monitor you when you start or stop taking Esomeprazole Krka.
- Cilostazol (used to treat intermittent claudication – a pain in your legs when you walk which is caused by an insufficient blood supply).
- Cisapride (used for indigestion and heartburn).
- 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 Krka treatment.
- Clopidogrel (used to prevent blood clots (thrombi)).
- Tacrolimus (organ transplantation).
- Rifampicin (to treat tuberculosis).
- St John's Wort (*Hypericum perforatum*) (used to treat depression).

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as Esomeprazole Krka to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you tell your doctor if you are taking any other medicines.

Esomeprazole Krka with food and drink
You can take your capsules with food or on an empty stomach.

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 taking this medicine. Your doctor will decide whether you can take Esomeprazole Krka during this time.
It is not known if Esomeprazole Krka passes into breast milk. Therefore, you should not take Esomeprazole Krka if you are breast-feeding.

Driving and using machines
Esomeprazole Krka 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 or rarely occur (see section 4). If affected, you should not drive or use machines.

Esomeprazole Krka contains sucrose and sodium
Esomeprazole Krka 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, talk to your doctor before taking this medicine.
This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially "sodium-free".

3. How to take Esomeprazole Krka

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- If you are taking this medicine for a long time, your doctor will want to monitor you (particularly if you are taking it for more than a year).
- If your doctor has told you to take this medicine as and when you need it, tell your doctor if your symptoms change.

How much to take
- Your doctor will tell you how many capsules to take and how long to take them for. This will

depend on your condition, how old you are and how well your liver works.
- The recommended doses are given below.

Use in adults aged 18 and above

To treat heartburn caused by gastro-esophageal reflux disease (GERD):
- If your doctor has found that your food pipe (gullet) has been slightly damaged, the recommended dose is one Esomeprazole Krka 40 mg gastro-resistant capsule once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks if your gullet has not yet healed.
- The recommended dose once the gullet has healed is one Esomeprazole Krka 20 mg gastro-resistant capsule once a day.
- If your gullet has not been damaged, the recommended dose is one Esomeprazole Krka 20 mg gastro-resistant capsule each day. Once the condition has been controlled, your doctor may tell you to take your medicine as and when you need it, up to a maximum of one Esomeprazole Krka 20 mg gastro-resistant capsule each day.
- If you have severe liver problems, your doctor may give you a lower dose.

To treat ulcers caused by *Helicobacter pylori* infection and to stop them coming back:
- The recommended dose is one Esomeprazole Krka 20 mg gastro-resistant capsule 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 dose is one Esomeprazole Krka 20 mg gastro-resistant capsule once a day for 4 to 8 weeks.

To prevent stomach ulcers if you are taking NSAIDs (Non-Steroidal Anti-Inflammatory Drugs):
- The recommended dose is one Esomeprazole Krka 20 mg gastro-resistant capsule once a day.

To treat too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome):
- The recommended dose is one Esomeprazole Krka 40 mg gastro-resistant capsule twice a day.
- Your doctor will adjust the dose depending on your needs and will also decide how long you need to take the medicine for. The maximum dose is 80 mg twice a day.

Prolonged treatment after prevention of rebleeding of ulcers with intravenous esomeprazole:
- The recommended dose is one Esomeprazole Krka 40 mg capsule once a day for 4 weeks.

Use in adolescents aged 12 or above

To treat heartburn caused by gastroesophageal reflux disease (GERD):
- If your doctor has found that your food pipe (gullet) has been slightly damaged, the recommended dose is one Esomeprazole Krka 40 mg gastro-resistant capsule once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks if your gullet has not yet healed.
- The recommended dose once the gullet has healed is one Esomeprazole Krka 20 mg gastro-resistant capsule once a day.
- If your gullet has not been damaged, the recommended dose is one Esomeprazole Krka 20 mg gastro-resistant capsule each day.
- If you have severe liver problems, your doctor may give you a lower dose.

To treat ulcers caused by *Helicobacter pylori* infection and to stop them coming back:
- The recommended dose is one Esomeprazole Krka 20 mg gastro-resistant capsule twice a day for one week.
- Your doctor will also tell you to take antibiotics for example amoxicillin and clarithromycin.

Taking this medicine

- You can take your capsules at any time of the day.
- You can take your capsules with food or on an empty stomach.
- Swallow your capsules whole with a drink of water. Do not chew or crush the capsules. This is because the capsules contain coated pellets which stop the medicine from being broken down by the acid in your stomach. It is important not to damage the pellets.

What to do if you have trouble swallowing the capsules
- If you have trouble swallowing the capsules:
  - Open the capsule and empty the pellets into half a glass of still (non-fizzy) water. Do not use any other liquids.
  - Then drink the mixture straight away or within 30 minutes. Always stir the mixture just before drinking it.
  - To make sure that you have drunk all of the medicine, rinse the glass very well with half a glass of water and drink it. The solid pieces contain the medicine - do not chew or crush them.
- If you cannot swallow at all, the pellets can be mixed with some water and put into a syringe. They can then be given to you through a tube directly into your stomach ("gastric tube").

Use in children under the age of 12 years
Esomeprazole Krka is not recommended for children less than 12 years old.

Elderly
Dose adjustment is not required in the elderly.

If you take more Esomeprazole Krka than you should
If you take more Esomeprazole Krka than prescribed by your doctor, talk to your doctor or pharmacist straight away.

If you forget to take Esomeprazole Krka
- If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the following serious side effects, stop taking Esomeprazole Krka and contact a doctor immediately:
- 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.
- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction).
  These effects are rare, and may affect up to 1 in 1 000 people.
- Sudden onset 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 might affect up to 1 in 10 000 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).
- Benign polyps in the stomach.

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).
- 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 Krka 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.
- Eyesight problems such as blurred vision.
- 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 (pancytopenia) including agranulocytosis (lack of white blood cells).
- Aggression.
- Seeing, feeling or hearing things that are not there (hallucinations).
- 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, drug reaction with eosinophilia and systemic symptoms).
- Muscle weakness.
- Severe kidney problems.
- Enlarged breasts in men.

Not known (frequency cannot be estimated from the available data)
- If you are on Esomeprazole Krka 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, 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.
- Inflammation in the gut (leading to diarrhoea).
- Rash, possibly with pain in the joints.

Esomeprazole Krka 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.

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 HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Esomeprazole Krka

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

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

Blister pack consisting of OPA/Al/PE + DES film/Al foil
This medicinal product does not require any special temperature storage conditions.
Store in the original package in order to protect from moisture.

Blister pack consisting of OPA/Al/PVC/Al foil
Do not store above 30°C.
Store in the original package in order to protect from moisture.

HDPE container
This medicinal product does not require any special temperature storage conditions.
Keep the container tightly closed in order to protect from moisture.
After first opening of the container, the product should be used within 6 months.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Esomeprazole Krka contains
- The active substance is esomeprazole. Each hard gastro-resistant capsule contains 20 mg or 40 mg esomeprazole (as esomeprazole magnesium dihydrate).
- The other ingredients are sugar spheres (sucrose and maize starch), povidone K30, sodium laurilsulfate, poly(vinyl alcohol), titanium dioxide (E171), macrogol 6000, macrogol 3000, talc (E553b), heavy magnesium carbonate, polysorbate 80 (E433) and methacrylic acid – ethyl acrylate copolymer (1:1) dispersion 30 per cent in pellets in the capsule core, and gelatin, titanium dioxide (E171) and red iron oxide (E172) in the capsule shell. See section 2 "Esomeprazole Krka contains sucrose and sodium".

What Esomeprazole Krka looks like and contents of the pack
The body and cap of the 20 mg hard gastro-resistant capsules are slightly pink. The capsules contain white to almost white pellets. Capsule size: no. 3.
The body and cap of the 40 mg hard gastro-resistant capsules are off-pink. The capsules contain white to almost white pellets. Capsule size: no. 1.
The capsules are available in boxes of 7, 10, 14, 15, 28, 30, 50, 50x1, 56, 60, 90, 98 and 100 capsules in blister packs, and boxes of 98 capsules and a desiccant capsule in HDPE containers. Do not eat the desiccant capsule provided in the container.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Manufacturer
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This medicine is authorised in the Member States of the European Economic Area under the following names:

Belgium	Esomeprazole Teva
Cyprus, Ireland	Esomeprazole Krka
Germany	Esomeprazol TAD
Greece	Esolib
Italy	Esomeprazolo Krka
Malta	TAZOKAP
Netherlands	Esomeprazol Sandoz
Slovenia	Emozul
Sweden	Esomeprazol Krka

This leaflet was last revised in

The following information is intended for healthcare professionals only:

Administration through gastric tube *(gastric tubes with minimum 16 Charrière (≥ 16 CH) are recommended*)

1. Open the capsule and empty the pellets into an appropriate syringe and fill the syringe with approximately 25 ml water and approximately 5 ml air.
   For some tubes, dispersion in 50 ml water is needed to prevent the pellets from clogging the tube.
2. Immediately shake the syringe to evenly distribute the granules throughout the suspension.
3. Hold the syringe with the tip up and check that the tip has not clogged.
4. Attach the syringe to the tube whilst maintaining the above position.
5. Shake the syringe and position it with the tip pointing down. Immediately inject 5 – 10 ml into the tube. Invert the syringe after injection and shake (the syringe must be held with the tip pointing up to avoid clogging of the tip).
6. Turn the syringe with the tip down and immediately inject another 5 – 10 ml into the tube. Repeat this procedure until the syringe is empty.
7. Fill the syringe with 25 ml of water and 5 ml of air and repeat step 5 if necessary to wash down any sediment left in the syringe. For some tubes, 50 ml water is needed.