

PACKAGE LEAFLET: INFORMATION FOR THE USER

Esomeprazole 20mg gastro-resistant capsules, hard (Esomeprazole (as magnesium dihydrate))

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Esomeprazole is and what it is used for
2. Before you take Esomeprazole
3. How to take Esomeprazole
4. Possible side effects
5. How to store Esomeprazole
6. Further information

1. WHAT ESOMEPRAZOLE IS AND WHAT IT IS USED FOR

Esomeprazole belongs to a group of medicines called "proton pump inhibitors". They work by reducing the amount of acid that your stomach produces.

Esomeprazole is used for:

- "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.
This medicine is given to:
 - heal your gullet if it has become damaged or inflamed
 - stop these conditions coming back
 - give you relief from the unpleasant symptoms that often occur with these conditions
- 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 this medicine in combination with certain antibiotics to:
 - heal duodenal ulcers associated with bacteria *Helicobacter pylori*
 - prevent the reoccurrence of ulcers associated with this bacteria
- Stomach ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). This medicine is given to:
 - heal ulcers in your stomach caused by NSAIDs
 - stop stomach and duodenal ulcers from forming if you are taking NSAIDs
 - Prolonged treatment after prevention of rebleeding of ulcers with intravenous esomeprazole.
 - Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).

2. BEFORE YOU TAKE ESOMEPRAZOLE

Do not take Esomeprazole

- If you are allergic (hypersensitive) to esomeprazole or any of the other ingredients of Esomeprazole.
- If you are allergic to other proton pump inhibitor medicines.
- If you are taking atazanavir (a medicine used to treat HIV).

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

Take special care with Esomeprazole

Check with your doctor or pharmacist before taking Esomeprazole if:

- You have severe liver problems.
- You have severe kidney problems.

Esomeprazole may hide the symptoms of other diseases.

Therefore, if any of the following happen to you before you start taking Esomeprazole or while you are taking them, 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 stool (blood-stained faeces).

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

If diarrhoea occurs during the treatment with Esomeprazole contact your doctor immediately, as treatment with proton pump inhibitors may lead to a slightly increased risk of gastrointestinal infections such as *Salmonella* and *Campylobacter*.

Taking a proton pump inhibitor like Esomeprazole, 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).

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is because Esomeprazole can affect the way some medicines work and some medicines can have an effect on Esomeprazole.

Do not take Esomeprazole if you are taking the following medicine:

- Atazanavir (used to treat HIV).

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

- 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 taking Esomeprazole.
- 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.
- Cisapride (used for indigestion and heartburn).

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

Taking Esomeprazole with food and drink

You can take your capsule with food or on an empty stomach.

Pregnancy and breastfeeding

Before taking Esomeprazole, tell your doctor if you are pregnant or trying to get pregnant. Ask your doctor or pharmacist for advice before taking any medicine. Your doctor will decide whether you can take Esomeprazole during this time. It is not known if Esomeprazole passes into breast milk. Therefore, you should not take Esomeprazole if you are breastfeeding.

Driving and using machines

Esomeprazole is not likely to affect you being able to drive or use any tools or machines.

Important information about some of the ingredients of Esomeprazole

Esomeprazole contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE ESOMEPRAZOLE

Always take Esomeprazole exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Esomeprazole is not recommended for children less than 12 years old.
- 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.

Taking this medicine

- You can take your medicine at any time of the day.
- You can take your capsules with food or on an empty stomach.
- Swallow your capsules 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. 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 capsule can be mixed with some water and put into a syringe. It can then be given to you through a tube directly into your stomach ("gastric tube").

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 usual doses are given below.

To treat heartburn caused by gastro-esophageal reflux disease (GERD):

Adults and children aged 12 or above:

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the usual dose is one Esomeprazole 40mg capsule once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks if the gullet has not yet healed.
- The usual dose once the gullet has healed is one Esomeprazole 20mg capsule once a day.
- If your gullet has not been damaged, the usual dose is one Esomeprazole 20mg 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 20mg 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:

- Adults aged 18 or above: the usual dose is one Esomeprazole 20mg capsule twice a day for one week.
- Your doctor will also tell you to take antibiotics called amoxicillin and clarithromycin.

To treat stomach ulcers caused by NSAIDs (Non-Steroidal Anti-Inflammatory Drugs):

- Adults aged 18 and above: the usual dose is one Esomeprazole 20mg capsule once a day for 4 to 8 weeks.

To prevent stomach ulcers if you are taking NSAIDs (Non-Steroidal Anti-Inflammatory Drugs):

- Adults aged 18 and above: the usual dose is one Esomeprazole 20mg capsule once a day.

To be used as prolonged treatment after prevention of rebleeding of ulcers with intravenous esomeprazole:

- Adults aged 18 and above: the usual dose is one Esomeprazole 40mg capsule once a day for 4 weeks.

To treat too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome):

- Adults aged 18 and above: the usual dose is one Esomeprazole 40mg 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 80mg twice a day.

If you take more Esomeprazole than you should

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

If you forget to take Esomeprazole

- 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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

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

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties to swallow (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, affecting less than 1 in 1,000 people.

Other side effects include:

Very common:	Affects more than 1 user in 10
Common:	Affects 1 to 10 users in 100
Uncommon:	Affects 1 to 10 users in 1,000
Rare:	Affects 1 to 10 users in 10,000
Very rare:	Affects less than 1 user in 10,000
Not known:	Frequency cannot be estimated from available data

Common

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

Uncommon

- 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 is used in high doses and over long duration).

Rare

- Blood problems such as a reduced number of white cells (leucopenia) or platelets (thrombocytopenia). This can cause weakness, bruising or making 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

- Changes in blood count including lack of white blood cells (agranulocytosis) and a reduction in the number of red and white blood cells, as well as platelets (pancytopenia).
- 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).
- Muscle weakness.
- Severe kidney problems.
- Enlarged breasts in men.

Frequency not known

If you are taking Esomeprazole 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.

Esomeprazole 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.

Do not be concerned by this list of possible side effects. You may not get 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 or pharmacist.

5. HOW TO STORE ESOMEPRAZOLE

Keep out of the sight and reach of children.

Do not use Esomeprazole after the expiry date (Exp) which is stated on the packaging. The expiry date refers to the last day of that month.

Do not store above 30°C.

Store in the original package in order to protect from moisture.

If your tablets appear to be discoloured, damaged or show any other signs of deterioration, please return these to your pharmacist who will advise you further.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

If you have any left-over/unused tablets, please return these to pharmacist for safe disposal.

6. FURTHER INFORMATION

What Esomeprazole contains

- The active substance is esomeprazole. Each gastro-resistant capsule, hard, contains 20mg esomeprazole (as magnesium dihydrate).
- The other ingredients are:
 - in the capsule core (pellets): sucrose, maize starch, povidone K30, sodium laurilsulfate, polyvinyl alcohol, titanium dioxide (E171), macrogol 3000, macrogol 6000, talc, magnesium carbonate, methacrylic acid – ethyl acrylate copolymer (1:1), dispersion 30% and polysorbate 80
 - in the capsule shell: gelatin, titanium dioxide (E171) and red iron oxide (E172)

What Esomeprazole looks like and contents of the pack

The body and cap of the 20mg gastro-resistant capsules, hard, are slightly pink. The capsules contain white to almost white pellets.

Your medicine is available in blister packs containing 28 capsules in an over labeled outer carton.

Manufacturer

Manufactured by: KRKA, d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto, Slovenia

Procured from within the EU by the Parallel Product Authorisation holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

The product is repackaged by: Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, South Yorkshire, DN3 1QR, UK.

Distributed by: Eurodrug Ltd, Santry, Dublin 9.

PPA No: 1151/146/1

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Esomeprazole 20mg gastro-resistant capsules, hard (Esomeprazole (as magnesium dihydrate))

Your medicine is available using the name Esomeprazole 20mg gastro-resistant capsules, hard but will be referred to as Esomeprazole throughout this leaflet.

Read all of this leaflet carefully before you start taking this medicine.

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- If you have any further questions, ask your doctor or pharmacist.
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1. WHAT ESOMEPRAZOLE IS AND WHAT IT IS USED FOR

Esomeprazole belongs to a group of medicines called "proton pump inhibitors". They work by reducing the amount of acid that your stomach produces.

Esomeprazole is used for:

- "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.
This medicine is given to:
 - heal your gullet if it has become damaged or inflamed
 - stop these conditions coming back
 - give you relief from the unpleasant symptoms that often occur with these conditions
- 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 this medicine in combination with certain antibiotics to:
 - heal duodenal ulcers associated with bacteria *Helicobacter pylori*
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- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).

2. BEFORE YOU TAKE ESOMEPRAZOLE

Do not take Esomeprazole

- If you are allergic (hypersensitive) to esomeprazole or any of the other ingredients of Esomeprazole.
- If you are allergic to other proton pump inhibitor medicines.
- If you are taking atazanavir (a medicine used to treat HIV).

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

Take special care with Esomeprazole

Check with your doctor or pharmacist before taking Esomeprazole if:

- You have severe liver problems.
- You have severe kidney problems.

Esomeprazole may hide the symptoms of other diseases.

Therefore, if any of the following happen to you before you start taking Esomeprazole or while you are taking them, 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 stool (blood-stained faeces).

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

If diarrhoea occurs during the treatment with Esomeprazole contact your doctor immediately, as treatment with proton pump inhibitors may lead to a slightly increased risk of gastrointestinal infections such as *Salmonella* and *Campylobacter*.

Taking a proton pump inhibitor like Esomeprazole, 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).

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is because Esomeprazole can affect the way some medicines work and some medicines can have an effect on Esomeprazole.

Do not take Esomeprazole if you are taking the following medicine:

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

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- 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.
- 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.
- Cisapride (used for indigestion and heartburn).

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

Taking Esomeprazole with food and drink

You can take your capsule with food or on an empty stomach.

Pregnancy and breastfeeding

Before taking Esomeprazole, tell your doctor if you are pregnant or trying to get pregnant. Ask your doctor or pharmacist for advice before taking any medicine. Your doctor will decide whether you can take Esomeprazole during this time. It is not known if Esomeprazole passes into breast milk. Therefore, you should not take Esomeprazole if you are breastfeeding.

Driving and using machines

Esomeprazole is not likely to affect you being able to drive or use any tools or machines.

Important information about some of the ingredients of Esomeprazole

Esomeprazole contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE ESOMEPRAZOLE

Always take Esomeprazole exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Esomeprazole is not recommended for children less than 12 years old.
- 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.

Taking this medicine

- You can take your medicine at any time of the day.
- You can take your capsules with food or on an empty stomach.
- Swallow your capsules 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.
 - 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 capsule can be mixed with some water and put into a syringe. It can then be given to you through a tube directly into your stomach ("gastric tube").

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 usual doses are given below.

To treat heartburn caused by gastro-esophageal reflux disease (GERD):

Adults and children aged 12 or above:

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the usual dose is one Esomeprazole 40mg capsule once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks if the gullet has not yet healed.
- The usual dose once the gullet has healed is one Esomeprazole 20mg capsule once a day.
- If your gullet has not been damaged, the usual dose is one Esomeprazole 20mg 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 20mg 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:

- Adults aged 18 or above: the usual dose is one Esomeprazole 20mg capsule twice a day for one week.
- Your doctor will also tell you to take antibiotics called amoxicillin and clarithromycin.

To treat stomach ulcers caused by NSAIDs (Non-Steroidal Anti-Inflammatory Drugs):

- Adults aged 18 and above: the usual dose is one Esomeprazole 20mg capsule once a day for 4 to 8 weeks.

To prevent stomach ulcers if you are taking NSAIDs (Non-Steroidal Anti-Inflammatory Drugs):

- Adults aged 18 and above: the usual dose is one Esomeprazole 20mg capsule once a day.

To be used as prolonged treatment after prevention of rebleeding of ulcers with intravenous esomeprazole:

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To treat too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome):

- Adults aged 18 and above: the usual dose is one Esomeprazole 40mg 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 80mg twice a day.

If you take more Esomeprazole than you should

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

If you forget to take Esomeprazole

- 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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

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

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties to swallow (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, affecting less than 1 in 1,000 people.

Other side effects include:

Very common:	Affects more than 1 user in 10
Common:	Affects 1 to 10 users in 100
Uncommon:	Affects 1 to 10 users in 1,000
Rare:	Affects 1 to 10 users in 10,000
Very rare:	Affects less than 1 user in 10,000
Not known:	Frequency cannot be estimated from available data

Common

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

Uncommon

- 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 is used in high doses and over long duration).

Rare

- Blood problems such as a reduced number of white cells (leucopenia) or platelets (thrombocytopenia). 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

- Changes in blood count including lack of white blood cells (agranulocytosis) and a reduction in the number of red and white blood cells, as well as platelets (pancytopenia).
- 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).
- Muscle weakness.
- Severe kidney problems.
- Enlarged breasts in men.

Frequency not known

If you are taking Esomeprazole 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.

Esomeprazole 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.

Do not be concerned by this list of possible side effects. You may not get 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 or pharmacist.

5. HOW TO STORE ESOMEPRAZOLE

Keep out of the sight and reach of children.

Do not use Esomeprazole after the expiry date (Exp) which is stated on the blister and carton. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture.

If your tablets appear to be discoloured, damaged or show any other signs of deterioration, please return these to your pharmacist who will advise you further.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

If you have any left-over/unused tablets, please return these to pharmacist for safe disposal.

6. FURTHER INFORMATION

What Esomeprazole contains

- The active substance is esomeprazole. Each gastro-resistant capsule, hard, contains 20mg esomeprazole (as magnesium dihydrate).
- The other ingredients are:
 - in the capsule core (pellets): sucrose, maize starch, Povidone K30, sodium laurilsulfate, poly(vinyl alcohol), titanium dioxide (E171), macrogol 3000, macrogol 6000, talc, heavy magnesium carbonate, methacrylic acid – ethyl acrylate copolymer (1:1), dispersion 30% and polysorbate 80
 - in the capsule shell: gelatine, titanium dioxide (E171) and red iron oxide (E172)

What Esomeprazole looks like and contents of the pack

The body and cap of the 20mg gastro-resistant capsules, hard, are slightly pink. The capsules contain white to almost white pellets.

Esomeprazole is available in blister packs containing 28 or 30 gastro-resistant capsules, hard in an outer carton.

Manufacturer

Manufactured by: KRKA, d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto, Slovenia

Procured from within the EU by the Parallel Product Authorisation holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

The product is repackaged by: Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, South Yorkshire, DN3 1QR, UK.

Distributed by: Eurodrug Ltd, Santry, Dublin 9.

PPA No: 1151/146/1

This medicinal product is authorized in the Member States of the EEA under the following names:

Name of the Member State	Name of the Medicinal product
Denmark	Esomeprazol Krka
Austria	Esomeprazol Krka
Bulgaria	Emanera
Cyprus	Esodec
Czech Republic	Emanera
Estonia	Emanera
Finland	Esomeprazol Krka
Greece	Esodec
Hungary	Emanera
Ireland	Nexazole 20mg Gastro-resistant capsules, hard
Latvia	Emanera
Lithuania	Emanera
Norway	Esomeprazol Krka
Poland	Emanera
Romania	Emanera
Slovenia	Emanera
Slovak Republic	Emanera 20mg tvrde gastrorezistentne kapsuly

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