

PACKAGE LEAFLET

Package leaflet: Information for the patient

Esomeprazole Teva Pharma 20 mg Gastro-resistant Tablets

Esomeprazole Teva Pharma 40 mg Gastro-resistant Tablets

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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Esomeprazole Teva Pharma is and what it is used for
2. What you need to know before you take Esomeprazole Teva Pharma
3. How to take Esomeprazole Teva Pharma
4. Possible side effects
5. How to store Esomeprazole Teva Pharma
6. Contents of the pack and other information

1. What Esomeprazole Teva Pharma is and what it is used for

Esomeprazole Teva Pharma 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 Teva Pharma 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.
- 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 Teva Pharma 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 Teva Pharma

Do not take Esomeprazole Teva Pharma:

- 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).

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Esomeprazole Teva Pharma:

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

Esomeprazole Teva Pharma may hide the symptoms of other diseases. **Therefore, if any of the following happen to you before you start taking Esomeprazole Teva Pharma 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 Teva Pharma “on demand” you should contact your doctor if your symptoms continue or change in character.

Taking a proton pump inhibitor like Esomeprazole Teva Pharma, 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 Teva Pharma. Remember to also mention any other ill-effects like pain in your joints.

Other medicines and Esomeprazole Teva Pharma

Tell your doctor or pharmacist 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 Teva Pharma can affect the way some medicines work and some medicines can have an effect on Esomeprazole Teva Pharma.

Do not take Esomeprazole Teva Pharma if you are taking a medicine containing nelfinavir (used to treat HIV infection).

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

- Atazanavir (used to treat HIV infection).
- Clopidogrel (used to prevent blood clots).
- 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 Teva Pharma.
- 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 Teva Pharma.
- 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).
- Digoxin (used for heart problems).
- 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 Teva Pharma treatment.
- Tacrolimus (organ transplantation).
- Rifampicin (used for treatment of 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 Teva Pharma to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you tell your doctor about any other medicines you are taking.

Esomeprazole Teva Pharma with food and drink

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

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, 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 Teva Pharma during this time. It is not known if esomeprazole passes into breast milk. Therefore, you should not take Esomeprazole Teva Pharma if you are breastfeeding.

Driving and using machines

Esomeprazole Teva Pharma 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 Teva Pharma contains sucrose and lactose

Esomeprazole Teva Pharma Gastro-resistant Tablets contain sucrose and lactose, which are types 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.

3. How to take Esomeprazole Teva Pharma

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 tablets 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.

Adults aged 18 and 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 Teva Pharma 40 mg Gastro-resistant Tablet 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 Teva Pharma 20 mg Gastro-resistant Tablet once a day.
- If your gullet has not been damaged, the recommended dose is one Esomeprazole Teva Pharma 20 mg gastro-resistant tablet 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 Teva Pharma 20 mg gastro-resistant tablet 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 Teva Pharma 20 mg Gastro-resistant Tablet 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 Teva Pharma 20 mg Gastro-resistant Tablet 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 Teva Pharma 20 mg Gastro-resistant Tablet 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 Teva Pharma 40 mg Gastro-resistant Tablet 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 Teva Pharma 40 mg Tablet once a day for 4 weeks.

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 Teva Pharma 40 mg Gastro-resistant Tablet 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 Teva Pharma 20 mg gastro-resistant tablet once a day.
- If your gullet has not been damaged, the recommended dose is one Esomeprazole Teva Pharma 20 mg gastro-resistant tablet 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 Teva Pharma 20 mg gastro-resistant tablet 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 tablets at any time of the day.
- You can take your tablets with food or on an empty stomach.

- Swallow your tablets whole with a drink of water. Do not chew or crush the tablets. This is because the tablets 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 tablets

- If you have trouble swallowing the tablets:
 - Put them into a glass of still (non-fizzy) water. Do not use any other liquids.
 - Stir until the tablets break up (the mixture will not be clear). 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 tablet 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').

Children under the age of 12 years

Esomeprazole Teva Pharma gastro-resistant tablets are not recommended for children less than 12 years old

Elderly

Dose adjustment is not required in the elderly.

If you take more Esomeprazole Teva Pharma than you should

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

If you forget to take Esomeprazole Teva Pharma

- 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 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 Teva Pharma 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).
- 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 Teva Pharma 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 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).
- Muscle weakness.
- Severe kidney problems.
- Enlarged breasts in men.

Not known: frequency cannot be estimated from the available data

- If you are on Esomeprazole Teva Pharma 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.
- Inflammation in the gut (leading to diarrhoea).
- Rash, possibly with pain in the joints.

Esomeprazole Teva Pharma 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Esomeprazole Teva Pharma

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 carton, bottle and blister after EXP. The expiry date refers to the last day of that month.

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

This medicine should be used no longer than 100 days after first opening of the bottle.

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. Content of the pack and other information

What Esomeprazole Teva Pharma contains

- The active substance is esomeprazole. Esomeprazole Teva Pharma Gastro-resistant Tablets come in two strengths containing 20 mg or 40 mg of esomeprazole (as esomeprazole magnesium).
- The other ingredients are:
Seal coated sugar spheres: Sugar spheres (sucrose and maize starch), ethylcellulose, magnesium stearate

Drug coat: Povidone K 90, magnesium oxide, light (E 530)

Barrier coat: Povidone, magnesium oxide, light (E 530), magnesium stearate

Enteric coat: Methacrylic acid - ethyl acrylate copolymer (1:1) dispersion 30 per cent (contains sodium laurilsulfate and polysorbate 80), diethyl phthalate, talc (E 553b)

Tablet core: Silicified microcrystalline cellulose (microcrystalline cellulose and colloidal anhydrous silica), starlac (lactose monohydrate and maize starch), copovidone K 28, macrogol 8000, crospovidone, silica colloidal, anhydrous, magnesium stearate

Film coat: Hypromellose (E 464), macrogol 8000, talc (E 553b), titanium dioxide (E 171), silica colloidal, anhydrous, iron oxide red (E172)

Imprint: Opacode S-1-17823 black ink (contains propylene glycol, iron oxide black (E172), shellac glaze)

What Esomeprazole Teva Pharma looks like and contents of the pack

Esomeprazole Teva Pharma 20 mg Gastro-resistant Tablets

Brick-red coloured, round shape, biconvex, film-coated tablet, imprinted with “20” on one side and plain on the other side.

Esomeprazole Teva Pharma 40 mg Gastro-resistant Tablets

Brick-red coloured, round shape, bevelled edge, biconvex, film-coated tablet, imprinted with “40” on one side and plain on the other side.

Blister (Aluminium/Aluminium) or HDPE container (HDPE container of neck finish and PP closure with induction sealing wad and a silica gel canister as desiccant).

Pack sizes:

20 mg, blister: 7, 14, 28, 30, 56, 60, 98, 100 Gastro-resistant Tablets

20 mg, HPDE container: 14, 28, 56, 98, 100 Gastro-resistant Tablets

40 mg, blister: 14, 28, 30, 56, 60, 98, 100 Gastro-resistant Tablets

40 mg, HPDE container: 14, 28, 56, 98, 100 Gastro-resistant Tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Teva Pharma B.V.

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Manufacturers

Torrent Pharma GmbH, Südwestpark 50, 90449 Nürnberg,
Germany

Merckle GmbH, Ludwig-Merckle-Strasse 3, D-89143
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74770 Opava-Komarov, Czech Republic.

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

Denmark	Esomeprazol Teva
France	ESOMEPRAZOLE TEVA SANTE 20 mg, comprimé gastro-resistant ESOMEPRAZOLE TEVA SANTE 40 mg, comprimé gastro-resistant
Germany	Esomeprazol Teva 20 mg magensaftresistente Tabletten Esomeprazol Teva 40 mg magensaftresistente Tabletten
Hungary	Omyprex 20 mg gyomornedv-ellenálló tabletta Omyprex 40 mg gyomornedv-ellenálló tabletta
Ireland	Esomeprazole Teva Pharma 20 mg Gastro-resistant Tablets Esomeprazole Teva Pharma 40 mg Gastro-resistant Tablets
Norway	Emazol 20mg enterotabletter Emazol 40mg enterotabletter
Portugal	Esomeprazol Teva
United Kingdom	Esomeprazole 20 mg gastro-resistant tablets Esomeprazole 40 mg gastro-resistant tablets

This leaflet was last revised in February 2017.

The following information is intended for healthcare professionals only:

Administration through gastric tube

1. Put the tablet 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 for approximately 2 minutes to disperse the tablet.
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.