Package leaflet: Information for the user

Esomeprazole Clonmel 20 mg gastro-resistant tablets
esomeprazole

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

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

Esomeprazole Clonmel contains the active substance esomeprazole. It belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces.

This medicine is used in adults for the short-term treatment of reflux symptoms (for example, heartburn and acid regurgitation).

Reflux is the backflow of acid from the stomach into the gullet ("foodpipe") which may become inflamed and painful. This may cause you symptoms such as a painful sensation in the chest rising up to your throat (heartburn) and a sour taste in the mouth (acid regurgitation).

Esomeprazole Clonmel is not meant to bring immediate relief. You may need to take the tablets for 2-3 days in a row before you feel better. You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

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

DO NOT take Esomeprazole Clonmel:

- If you are allergic to esomeprazole or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to medicines containing other proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole or omeprazole).

- If you are taking a medicine containing nelfinavir (used to treat HIV infection).
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking esomeprazole or other related medicines.

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

Warnings and precautions
Talk to your doctor before taking Esomeprazole Clonmel if:
- You have had a stomach ulcer or stomach surgery in the past.
- You have been taking treatment continuously for reflux or heartburn for 4 or more weeks.
- You have jaundice (yellowing of skin or eyes) or severe liver problems.
- You have severe kidney problems.
- You are aged over 55 years and have new or recently changed reflux symptoms or need to take a non-prescription indigestion or heartburn remedy treatment every day.
- You have ever had a skin reaction after treatment with a medicine similar to Esomeprazole Clonmel that reduces stomach acid.
- You are due to have an endoscopy or a urea breath test.
- You are due to have a specific blood test (Chromogranin A).

Tell your doctor immediately before or after taking this medicine, if you notice any of the following symptoms, which could be a sign of another, more serious, disease.
- You lose a lot of weight for no reason.
- You have problems or pain when swallowing.
- You get stomach pain or signs of indigestion such as nausea, fullness, bloating especially after food intake.
- You begin to vomit food or blood, which may appear as dark coffee grounds in your vomit.
- You pass black stools (blood-stained faeces).
- You have severe or persistent diarrhoea; esomeprazole has been associated with a small increased risk of infectious diarrhoea.
- 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 Clonmel. Remember to also mention any other ill-effects like pain in your joints.

Seek urgent medical attention if you experience chest pain with light-headedness, sweating, dizziness or shoulder pain with shortness of breath. This could be a sign of a serious condition with your heart.

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), have been reported in association with esomeprazole-treatment. Stop using Esomeprazole Clonmel and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

If any of the above apply to you (or you are not sure), talk to your doctor straight away.

Children and adolescents
This medicine should not be used by children and adolescents under 18 years of age.

Other medicines and Esomeprazole Clonmel
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This is because this medicine can affect the way some medicines work and some medicines can have an effect on it.

Do not take this medicine if you are also taking a medicine containing nelfinavir (used to treat HIV infection).

You should specifically tell your doctor or pharmacist if you are taking clopidogrel (used to prevent blood clots).

Do not take this medicine with other medicines that limit the amount of acid produced in your stomach such as proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole or omeprazole) or an H_2 antagonist (e.g. ranitidine or famotidine).

You may take this medicine with antacids (e.g. magaldrate, alginic acid, sodium bicarbonate, aluminium hydroxide, magnesium carbonate or combinations of these) if needed.

Tell your doctor or pharmacist if you are taking any of the following medicines:
- Ketoconazole and itraconazole (used to treat infections caused by a fungus)
- Voriconazole (used to treat infections caused by a fungus) and clarithromycin (used to treat infections). Your doctor may adjust your dose of Esomeprazole Clonmel if you also have severe liver problems and are treated for a long period of time.
- Erlotinib (used to treat cancer)
- Methotrexate (used to treat cancer and rheumatic disorders)
- Digoxin (used for heart problems)
- Atazanavir, saquinavir (used to treat HIV infection)
- Citalopram, imipramine or clomipramine (used to treat depression)
- Diazepam (used to treat anxiety, relax muscles or in epilepsy)
- Phenytoin (used to treat epilepsy)
- 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 Clonmel
- Cilostazol (used to treat intermittent claudication - a condition where poor blood supply to the leg muscles causes pain and difficulty in walking)
- Cisapride (used for indigestion and heartburn)
- Rifampicin (used to treat tuberculosis)
- Tacrolimus (in cases of organ transplantation)
- St. John's wort (*Hypericum perforatum*) (used to treat depression)

Pregnancy and breast-feeding
As a precautionary measure, you should preferably avoid the use of Esomeprazole Clonmel during pregnancy. You should not use this medicine during breast-feeding.
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.

Driving and using machines
Esomeprazole Clonmel has a low likelihood of affecting your ability to drive or use machines. However, side effects such as dizziness and visual disturbances may uncommonly occur (see section 4). If affected, you should not drive or use machines.

Esomeprazole Clonmel contains lactose and sucrose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Esomeprazole Clonmel

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

How much to take
- The recommended dose is one tablet a day.
- Do not take more than this recommended dose of one tablet (20 mg) a day, even if you don't feel an improvement immediately.
- You may need to take the tablets for 2 or 3 days in a row before your reflux symptoms (for example, heartburn and acid regurgitation) get better.
- The treatment length is up to 14 days.
- When your reflux symptoms have completely gone you should stop taking this medicine.
- If your reflux symptoms get worse or do not improve after taking this medicine for 14 days in a row, you should consult a doctor.

If you have persistent or longstanding, frequently recurring symptoms even after treatment with this medicine, you should contact your doctor.

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

Alternative method of taking this medicine
- Put the tablet in a glass of still (non-fizzy) water. Do not use any other liquids.
- Stir until the tablet breaks 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 take more Esomeprazole Clonmel than you should
If you take more Esomeprazole Clonmel than recommended, talk to your doctor or pharmacist straight away. You may experience symptoms such as diarrhoea, stomach ache, constipation, feeling or being sick and weakness.

If you forget to take Esomeprazole Clonmel
If you forget to take a dose, take it as soon as you remember it, on the same day. 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 Clonmel and contact a doctor immediately:

- Sudden wheezing, swelling of your lips, tongue and throat, rash, fainting or difficulties in swallowing (severe allergic reaction, seen rarely).
- 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', seen very rarely.
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems, seen rarely.
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome), seen very rarely.

Talk to your doctor as soon as possible if you experience any of the following signs of infection:
This medicine 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 medicine at this time.

Other side effects include:

Common (may affect up to 1 in 10 people)

- Headache.
- Effects on your stomach or gut: diarrhoea, stomach ache, constipation, wind (flatulence).
- Feeling sick (nausea) or being sick (vomiting).
- Benign growths (polyps) in the stomach.

Uncommon (may affect up to 1 in 100 people)

- Swelling of the feet and ankles.
- Disturbed sleep (insomnia), feeling sleepy.
- Dizziness, tingling feelings such as "pins and needles".
- Spinning feeling (vertigo).
- Dry mouth.
- Increased liver enzymes shown in blood tests that check how the liver is working.
- Skin rash, lumpy rash (hives) and itchy skin.

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

- Blood problems such as a reduced number of white blood 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 on the inside of the mouth.
- An infection called "thrush" which can affect the gut and is caused by a fungus.

- Hair loss (alopecia).
- Skin rash on exposure to sunshine.
- Joint pain (arthralgia) or muscle pain (myalgia).
- Generally feeling unwell and lacking energy.
- Increased sweating.

Very rare (may affect up to 1 in 10 000 people)
- Low numbers of red blood cells, white blood cells, and platelets (a condition called pancytopenia)
- Aggression.
- Seeing, feeling or hearing things that are not there (hallucinations).
- Severe liver problems leading to liver failure and inflammation of the brain.
- Muscle weakness.
- Severe kidney problems.
- Enlarged breasts in men.

Not known (frequency cannot be estimated from the available data)
- Low levels of magnesium in the blood. This may cause weakness, being sick (vomiting), cramps, tremor and changes in heart rhythm (arrhythmias). If you have very low levels of magnesium, you may also have low levels of calcium and/or potassium in your blood.
- Inflammation of the gut (leading to diarrhoea).
- Rash, possibly with pain in the joints.

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:
Ireland: HPRA Pharmacovigilance, Website: www.hpra.ie
Malta: ADR Reporting, Website: www.medicinesauthority.gov.mt/adrportal
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Esomeprazole Clonmel

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

Store below 30 °C. Store this medicine in the original package, in order to protect from moisture.

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

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 Clonmel contains
The active substance is esomeprazole (as magnesium trihydrate). Each gastro-resistant tablet contains esomeprazole magnesium trihydrate equivalent to 20 mg esomeprazole.

The other ingredients are: sugar spheres (sucrose and maize starch), Hypromellose (E464), talc, polysorbate 80, magnesium stearate, methacrylic acid-ethyl acrylate copolymer (1:1), , glycerol monostearate, triethyl citrate, macrogol (E1521), lactose monohydrate, maize starch, microcrystalline cellulose, crospovidone, povidone, silica colloidal anhydrous, liquid paraffin (light), titanium dioxide (E171), iron oxide red (E172), iron oxide yellow (E172).

What Esomeprazole Clonmel looks like and contents of the pack
Esomeprazole Clonmel gastro-resistant tablets contain 20 mg of esomeprazole:
Tablets are oval, light pink, biconvex gastro-resistant tablets of approximately 14x7 mm with a debossed "E2" on one side.

Esomeprazole Clonmel is available in Alu (outer OPA film / inner PVC film) / Alu (heat seal lacquer) blisters of 7, 14 and 28 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer
LABORATORIOS LICONSA, S.A., Avda. Miralcampo, N°7, Polígono Industrial Miralcampo 19200 Azuqueca de Henares (Guadalajara), Spain
STADA Arzneimittel AG, Stadastrasse 2 – 18, 61118 Bad Vilbel, Germany

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

Czechia:	Esurap
Estonia:	Esomeprazole STADA
France:	ESOMEPRAZOLE EG LABO CONSEIL20 mg, comprimé gastrorésistant
Ireland:	Esomeprazole Clonmel 20 mg gastro-resistant tablets
Latvia:	Esomeprazole STADA 20 mg zarnās šķīstošās tabletes
Lithuania:	Esomeprazole STADA 20 mg skrandyje neirios tabletės
Malta:	Esomeprazole Clonmel 20 mg gastro-resistant tablets
Netherlands:	Trekpleister maagzuurremmende tabletten Esomeprazol 20 mg, maagsapresistente tabletten
Portugal:	Esomeprazol Stada 20 mg Comprimido gastrorresistente

This leaflet was last revised in August 2025.

FURTHER HELPFUL INFORMATION

What are the symptoms of heartburn?
The normal symptoms of reflux are a painful sensation in the chest rising up to your throat (heartburn) and a sour taste in the mouth (acid regurgitation).

Why do you get these symptoms?
Heartburn can be a result of eating too much, eating high fat food, eating too quickly and drinking lots of alcohol. You may also notice that when you lie down, that your heartburn gets worse. If you are overweight or smoke you increase the probability of suffering from heartburn.

What can I do to help relieve my symptoms?
- Eat healthier food and try to avoid spicy and fatty foods and large meals late before bedtime.
- Avoid fizzy drinks, coffee, chocolate and alcohol.
- Eat slowly and eat smaller portions.
- Try to lose weight.
- Stop smoking.

When should I seek advice or help?
- You should seek urgent medical advice if you experience chest pain with light-headedness, sweating, dizziness or shoulder pain with shortness of breath.
- If you experience any of the symptoms detailed in Section 2 of this leaflet and it advises you to talk to your doctor or pharmacist.
- If you are suffering from any of the side effects detailed in Section 4 which require medical attention.