

Package leaflet: Information for the user

Esomeprazole Clonmel 20mg gastro-resistant capsules, hard **Esomeprazole Clonmel 40mg gastro-resistant capsules, hard**

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

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

Esomeprazole Clonmel 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 Clonmel is used to treat the following conditions:

Adults

- 'Gastro-oesophageal reflux disease' (GORD). 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 Clonmel 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

- 'Gastro-oesophageal reflux disease' (GORD). 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 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 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 Clonmel if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Esomeprazole Clonmel.

Warnings and precautions

Talk to your doctor or pharmacist before taking Esomeprazole Clonmel:

- 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 Clonmel that reduces stomach acid.

Tell your doctor before taking this medicine, if you are due to have a specific blood test (Chromogranin A).

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

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

Children under the age of 12 years

Esomeprazole Clonmel should not be used in children younger than 12 years. More appropriate pharmaceutical forms of esomeprazole may be available (ask your doctor or pharmacist if you require further information).

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 Esomeprazole Clonmel can affect the way some medicines work and some medicines can have an effect on Esomeprazole Clonmel.

Do not take Esomeprazole Clonmel 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 or saquinavir (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 Clonmel.

- 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 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 Clonmel 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 Clonmel to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you tell your doctor about any other medicines you are taking.

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

Driving and using machines

Esomeprazole Clonmel 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 Clonmel contains sucrose, which is a type of sugar, propyl-p-hydroxybenzoate (E216) and methyl-p-hydroxybenzoate (E218):

- If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine,
- Parahydroxybenzoates may cause allergic reactions (possibly delayed).

3. How to take Esomeprazole Clonmel

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Esomeprazole Clonmel 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.

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.

Adults aged 18 and above

To treat heartburn caused by gastro-oesophageal reflux disease (GORD):

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the recommended dose is one capsule of Esomeprazole Clonmel 40 mg 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 capsule of Esomeprazole Clonmel 20 mg once a day.

- If your gullet has not been damaged, the recommended dose is one capsule Esomeprazole Clonmel 20 mg 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 capsule of Esomeprazole Clonmel 20 mg 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 capsule of Esomeprazole Clonmel 20 mg 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 capsule of Esomeprazole Clonmel 20 mg 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 capsule of Esomeprazole Clonmel 20 mg 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 capsule of Esomeprazole Clonmel 40 mg 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 capsule of Esomeprazole Clonmel 40 mg once a day for 4 weeks.

Adolescents aged 12 or above

To treat heartburn caused by gastro-oesophageal reflux disease (GORD):

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the recommended dose is one capsule of Esomeprazole Clonmel 40 mg 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 capsule of Esomeprazole Clonmel 20 mg once a day.
- If your gullet has not been damaged, the recommended dose is one capsule Esomeprazole Clonmel 20 mg 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 capsule of Esomeprazole Clonmel 20 mg 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 glass of water. Do not chew or crush the capsules or their contents. This is because the capsules contain coated granules which stop the medicine from being broken down by the acid in your stomach. It is important not to damage the granules.

What to do if you have trouble swallowing the capsules

- If you have trouble swallowing the capsules:
 - 1) Open the capsule carefully above a glass of still (non-fizzy) water and empty the content of the capsule (granules) into the glass. Do not use any other liquids.
 - 2) Stir. Then drink the mixture straight away or within 30 minutes. Always stir the mixture just before drinking it.

- 3) 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 content of 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').

Elderly

Dose adjustment is not required in the elderly.

Children under the age of 12 years

Esomeprazole Clonmel should not be used in children younger than 12 years. More appropriate pharmaceutical forms of esomeprazole may be available (ask your doctor or pharmacist if you require further information).

If you take more Esomeprazole Clonmel than you should

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

If you forget to take Esomeprazole Clonmel

- 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 Clonmel 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.

Esomeprazole Clonmel 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.

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 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 Clonmel 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 (subacute cutaneous lupus erythematosus).

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:

HPRRA 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 Clonmel

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

Do not store above 25°C.

Keep this medicine in the original container (blister) or keep the container tightly closed (bottle) in order to protect from moisture.

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

After opening of the bottle, the capsules should be used within 3 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 Clonmel contains

- The active substance is esomeprazole.

Esomeprazole Clonmel capsules come in two strengths containing 20 mg or 40 mg of esomeprazole (as magnesium dihydrate).

- The other ingredients are:

Capsule content:

sugar spheres (sucrose and maize starch), hypromellose, dimethicone emulsion 35% (containing dimethicone, propyl-p-hydroxybenzoate (E216), methyl-p-hydroxybenzoate (E218), sorbic acid, sodium benzoate, polyethylene glycol sorbitan monolaureate, octylphenoxy polyethoxy ethanol and propylene glycol), polysorbate 80, mannitol, diacetylated monoglycerides, talc, methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30 % (containing copolymer of methacrylic acid and ethyl acrylate, sodium lauryl sulfate and polysorbate 80), triethyl citrate and stearyl macroglycerides.

Capsule shell:

black iron oxide (E172), shellac, gelatin, yellow iron oxide (E172) and titanium dioxide (E171).

What Esomeprazole Clonmel looks like and contents of the pack

Esomeprazole Clonmel 20 mg capsules have an opaque yellow cap and an opaque white body.

“20 mg” is printed in black both on the cap and on the body.

Esomeprazole Clonmel 40 mg capsules have an opaque yellow cap and an opaque yellow body.

“40 mg” is printed in black both on the cap and on the body.

Your capsules will come in packs of:

Bottles of 28, 30, 90 or 98 capsules

Blisters of 7, 14, 15, 28, 30, 50, 56, 60, 90, 98 or 100 capsules

Not all pack size may be marketed.

Marketing Authorisation Holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer

Ethypharm, Z.I. de Saint-Arnoult, 28170 - Châteauneuf-en-Thymerais - France

Ethypharm, Chemin de la Poudrière, 76120 - Grand-Quevilly - France

– Prouvy – France

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

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

Austria	Esomeprazol STADA 20 mg - magensaftresistente Hartkapseln
	Esomeprazol STADA 40 mg - magensaftresistente Hartkapseln

Belgium	Esomeprazole EG 20 mg maagsapresistente capsule, hard Esomeprazole EG 40 mg maagsapresistente capsule, hard
Bulgaria	Ormus 20 mg стомашно-устойчиви капсули, твърди Ormus 40 mg стомашно-устойчиви капсули, твърди
France	Esomeprazole EG 20 mg, gélule gastro-résistante Esomeprazole EG 40 mg, gélule gastro-résistante
Ireland	Esomeprazole Clonmel 20 mg gastro-resistant capsules, hard Esomeprazole Clonmel 40 mg gastro-resistant capsules, hard
Italy	Esomeprazolo EG 20 mg capsule rigide gastroresistenti Esomeprazolo EG 40 mg capsule rigide gastroresistenti
Luxembourg	Esomeprazole EG 20 mg gélule gastro-résistante Esomeprazole EG 40 mg gélule gastro-résistante
Sweden	Esomeprazol STADA 20 mg harda enterokapslar Esomeprazol STADA 40 mg harda enterokapslar

This leaflet was last revised in March 2021.

The following information is intended for healthcare professionals only:

Administration through gastric tube

1. Add the contents of a capsule into approximately 25 ml or 50 ml of water. (For some tubes, dispersion in 50 ml water is needed to prevent the granules from clogging the tube). Stir.
2. Draw the suspension into a syringe and add approximately 5 ml of air.
3. Immediately shake the syringe for approximately 2 minutes to disperse the granules.
4. Hold the syringe with the tip up and check that the tip has not clogged.
5. Attach the syringe to the tube whilst maintaining the above position.
6. 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).
7. 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.
8. Fill the syringe with 25 ml of water and 5 ml of air and repeat step 6 if necessary to wash down any sediment left in the syringe. For some tubes, 50 ml water is needed.