

PACKAGE LEAFLET: INFORMATION FOR THE USER

Rabeprazole Clonmel 10mg Gastro-resistant Tablets **Rabeprazole Clonmel 20mg Gastro-resistant Tablets**

Rabeprazole sodium

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

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

Rabeprazole Clonmel tablets contain the active ingredient rabeprazole sodium. This belongs to a group of medicines called 'Proton Pump Inhibitors' (PPIs). They work by lowering the amount of acid that your stomach produces.

Rabeprazole Clonmel tablets are used to treat the following conditions:

- 'Gastro-oesophageal reflux disease' (GORD), which can include heartburn. GORD is caused when acid and food from your stomach escapes into your food pipe (oesophagus)
- Ulcers in your stomach or the upper part of your gut (intestine). If these ulcers are infected with bacteria called 'Helicobacter pylori' (H. Pylori), you will also be given antibiotics. Using Rabeprazole Clonmel tablets and antibiotics together gets rid of the infection and makes the ulcer heal. It also stops the infection and ulcer from coming back
- Zollinger-Ellison Syndrome where your stomach produces too much acid.

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

Do not take Rabeprazole Clonmel

- If you are allergic to rabeprazole sodium, or any of the other ingredients of this medicine (listed in section 6).
- If you are pregnant or think that you are pregnant.
- If you are breast-feeding.

Do not use Rabeprazole Clonmel if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Rabeprazole Clonmel.

Also see Pregnancy and breast-feeding section.

Warnings and precautions

Talk to your doctor or pharmacist before taking Rabeprazole Clonmel:

- If you are allergic to other proton pump inhibitor medicines or 'substituted benzimidazoles'.
- If you have a stomach tumour.
- If you have ever had liver problems.
- If you are taking atazanavir - for HIV infection.

- If you are due to have a specific blood test (Chromogranin A).
- If you have ever had a skin reaction after treatment with a medicine similar to Rabeprazole Clonmel that reduces stomach acid.

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 Rabeprazole Clonmel. Remember to also mention any other ill-effects like pain in your joints.

Taking a proton pump inhibitor like Rabeprazole 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).

Blood and liver problems have been seen in some patients but often get better when Rabeprazole Clonmel is stopped.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Rabeprazole Clonmel.

If you experience severe (watery or bloody) diarrhoea with symptoms such as fever, abdominal pain or tenderness, stop taking Rabeprazole Clonmel and see a doctor straight away.

Children

Rabeprazole Clonmel should not be used in children.

Other medicines and Rabeprazole Clonmel

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Ketoconazole or itraconazole – used to treat infections caused by a fungus. Rabeprazole Clonmel may lower the amount of this type of medicine in your blood. Your doctor may need to adjust your dose.
- Atazanavir - used to treat HIV-infection. Rabeprazole Clonmel may lower the amount of this type of medicine in your blood and they should not be used together.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Rabeprazole Clonmel.

Rabeprazole Clonmel with food and drink

Taking Rabeprazole Clonmel with or after food or drink does not have any effect on how the tablets work.

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.

- Do not use Rabeprazole Clonmel if you are pregnant or think you may be pregnant.
- Do not use Rabeprazole Clonmel if you are breast-feeding or planning to breast-feed.

Driving and using machines

You may feel sleepy while taking Rabeprazole Clonmel. If this happens, do not drive or use any tools or machines.

3. How to take Rabeprazole Clonmel

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

Taking this medicine

- Only remove a tablet from the blister strip when it is time to take your medicine.
- Swallow your tablets whole with a drink of water. Do not chew or crush the tablets.
- Your doctor will tell you how many tablets to take and how long to take them for. This will depend on your condition.
- If you are taking this medicine for a long time, your doctor will want to monitor you.

Adults and the Elderly**For 'gastro-oesophageal reflux disease' (GORD)****Treatment of moderate to severe symptoms (symptomatic GORD)**

- The recommended dose is one Rabeprazole Clonmel 10 mg tablet once a day for up to 4 weeks.
- Take the tablet in the morning before eating.
- If your symptoms do not resolve within four weeks, consult your doctor.
- If your condition returns after 4 weeks treatment, your doctor may tell you to take one Rabeprazole Clonmel 10 mg tablet as and when you require it.

Treatment of more severe symptoms (erosive or ulcerative GORD)

- The recommended dose is one Rabeprazole Clonmel 20 mg tablet once a day for 4 to 8 weeks.
- Take the tablet in the morning before eating.

Long-term treatment of symptoms (GORD maintenance)

- The recommended dose is one Rabeprazole Clonmel 10 mg or 20 mg tablet once a day for as long as your doctor has told you.
- Take the tablet in the morning before eating.
- Your doctor will want to see you at regular intervals to check your symptoms and dosage.

For ulcers of the stomach (peptic ulcers)

- The recommended dose is one Rabeprazole Clonmel 20 mg tablet once a day for 6 weeks.
- Take the tablet in the morning before eating.
- Your doctor may tell you to take Rabeprazole Clonmel for another 6 weeks if your condition does not improve.

For ulcers of the intestine (duodenal ulcers)

- The recommended dose is one Rabeprazole Clonmel 20 mg tablet once a day for 4 weeks.
- Take the tablet in the morning before eating.
- Your doctor may tell you to take Rabeprazole Clonmel for another 4 weeks if your condition does not improve.

For ulcers caused by H. Pylori infection and to stop them coming back

- The recommended dose is one Rabeprazole Clonmel 20 mg tablet twice a day for seven days.
- Your doctor will also tell you to take antibiotics called amoxicillin and clarithromycin.

For further information on the other medicines used for the H. Pylori treatment, see the individual product information leaflets.

Relief of symptoms will normally occur before the ulcer has completely healed. It is important that you do not stop taking the tablets until told to do so by your doctor.

Zollinger-Ellison Syndrome where excess acid is produced in the stomach

- The recommended dose is three Rabeprazole Clonmel 20 mg tablets once a day to start with.
- The dose may then be adjusted by your doctor depending on how you respond to the treatment.

If you are on long-term treatment you will need to see your doctor at regular intervals for review of your tablets and symptoms.

Use in children

The product should not to be used in children.

Patients with liver problems. You should consult your doctor who will take special care when beginning treatment with Rabeprazole Clonmel and while you continue to be treated with Rabeprazole Clonmel.

If you take more Rabeprazole Clonmel than you should

Do not take more tablets each day than you are prescribed. If you accidentally take more tablets than the prescribed dose, please consult your doctor or go to the hospital straight away. Always take the tablets and the carton with you to the hospital so that the doctor knows what has been taken.

If you forget to take Rabeprazole 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 and continue as usual.
- If you forget to take your medicine for more than 5 days, talk to your doctor before taking any more medicine.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking Rabeprazole Clonmel

Do not stop treatment early because your symptoms have got better. Your condition may not have been fully healed and may reoccur if you do not finish your course of treatment. Do not change the dosage or stop the medication without discussing it with your doctor first.

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. The side effects are usually mild and improve without you having to stop taking this medicine.

Stop taking Rabeprazole Clonmel and see a doctor straight away if you notice any of the following side effects - you may need urgent medical treatment:

Rare side effects (may affect up to 1 in 1,000 people)

- Allergic reactions – the signs may include: sudden swelling of your face, difficulty breathing or low blood pressure which may cause fainting or collapse.
- Frequent infections, such as a sore throat or high temperature (fever), or ulcers in your mouth or throat.
- Bruising or bleeding easily.

Very rare side effects (may affect up to 1 in 10,000 people)

- Severe skin blistering, or soreness or ulcers in your mouth and throat.

Other possible side effects:

Common (may affect up to 1 in 10 people)

- Infections.
- Difficulty sleeping (insomnia).
- Headache or feeling dizzy.
- Cough, runny nose (rhinitis) or sore throat (pharyngitis).

- Effects on your stomach or gut such as stomach pain, diarrhoea, wind (flatulence), feeling sick (nausea), being sick (vomiting) or constipation.
- Pain without any known cause, back pain.
- Weakness (asthenia) or flu-like symptoms.

Uncommon (may affect up to 1 in 100 people)

- Feeling nervous or drowsy.
- Chest infection (bronchitis).
- Painful and blocked sinuses (sinusitis).
- Dry mouth.
- Indigestion or belching.
- Skin rash or redness of the skin.
- Muscle or joint pain, leg cramps.
- Bladder infection (urinary tract infection).
- Chest pain.
- Chills or fever.
- Changes in how your liver is working (shown in blood tests).
- Fracture of the hip, wrist or spine.

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

- Loss of appetite (anorexia).
- Depression.
- Hypersensitivity (includes allergic reactions).
- Visual disturbance.
- Sore mouth (stomatitis) or taste disturbance.
- Upset stomach or stomach pain (gastritis).
- Liver problems such as inflammation of the liver (hepatitis), brain damage due to liver disease (hepatic encephalopathy) and yellowing of your skin and whites of your eyes (jaundice).
- Itchy rash or blistering skin.
- Sweating.
- Kidney problems.
- Weight gain.
- Changes in white blood cells (shown in blood tests) which may result in frequent infection.
- Reduction in blood platelets resulting in bleeding or bruising more easily than normal.

Other possible side effects (Not known: frequency cannot be estimated from the available data)

- Breast swelling in men.
- Fluid retention.
- Low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma (hyponatraemia).
- Confusion.
- Rash, possibly with pain in the joints.
- If you are on Rabeprazole 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, 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.

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 Rabeprazole Clonmel

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

Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the carton and blister foil. 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 Rabeprazole Clonmel contains

The active substance is rabeprazole sodium.

Each tablet contains 10 mg rabeprazole sodium, equivalent to 9.42 mg of rabeprazole.

Each tablet contains 20 mg rabeprazole sodium, equivalent to 18.85 mg of rabeprazole.

The other ingredients are:

Tablet core:

Mannitol (E421)

Magnesium Oxide, Light (E530)

Hydroxypropylcellulose (E463)

Povidone (E1201)

Magnesium Stearate (E572)

Tablet coating:

Ethylcellulose (E462)

Magnesium Oxide, Light (E530)

Hypromellose Phthalate

Diacetylated Monoglycerides (E472a)

Talc (E553b)

Titanium Dioxide (E171)

Iron Oxide Yellow (E172) (*for 20 mg*)

Iron Oxide Red (E172) (*for 10 mg*)

Carnauba Wax

What Rabeprazole Clonmel looks like and contents of the pack

Rabeprazole Clonmel 10mg gastro-resistant tablets are pink, round, biconvex gastro-resistant tablets with a diameter of 6 mm approximately.

Rabeprazole Clonmel 20mg gastro-resistant tablets are yellow, round, biconvex gastro-resistant tablets with a diameter of 7.5 mm approximately.

Rabeprazole Clonmel 10mg & 20mg gastro-resistant tablets are packed in OPA/Aluminium/PVC-Aluminium blisters of 7, 14, 28, 56 and 98 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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

Manufacturer:

Specifar S.A., 1, 28 Octovriou str., Ag. Varvara, 123 51 Athens, Greece

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

The Netherlands: Rabeprazolnatrium Specifar 10mg & 20mg maagsapresistente tabletten

Ireland: Rabeprazole Clonmel 10mg & 20mg gastro-resistant tablets

This leaflet was last revised in September 2016.