Package leaflet: Information for the user

Losec Control 20 mg gastro-resistant tablets
Omeprazole

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
Always use this medicine exactly as described in this leaflet or as your doctor 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 your doctor if you do not feel better or if you feel worse after 14 days.

What is in this leaflet:
1. What Losec Control is and what it is used for
2. What you need to know before you take Losec Control
3. How to take Losec Control
4. Possible side effects
5. How to store Losec Control
6. Contents of the pack and other information

1. WHAT LOSEC CONTROL IS AND WHAT IT IS USED FOR

Losec Control gastro-resistant tablets contains the active substance omeprazole. It belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces.

Losec Control 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 burning sensation in the chest rising up to the throat (heartburn) and a sour taste in the mouth (acid regurgitation).
It might be necessary to take the tablets for 2-3 consecutive days to achieve improvement of symptoms.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LOSEC CONTROL

Do not take Losec Control
- if you are allergic to omeprazole or any of the other ingredients of Losec Control (listed in section 6).
- if you are allergic to medicines containing other proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- if you are taking a medicine containing nelfinavir (for HIV infection).

If you are not sure, talk to your doctor or pharmacist before taking Losec Control.

Warnings and precautions

Tell your doctor before taking Losec Control if:

- you have ever had a skin reaction after treatment with a medicine similar to Losec Control 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 Losec Control. Remember to also mention any other ill-effects like pain in your joints.

- you are due to have a specific blood test (Chromogranin A).

Take special care with Losec Control
Do not take Losec Control for more than 14 days without consulting a doctor. If you do not experience relief, or if you experience a worsening of symptoms, consult your doctor.
Losec Control may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking Losec Control 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).
- You experience severe or persistent diarrhoea, as omeprazole has been associated with a small increase in infectious diarrhoea.
- You have had previous gastric ulcer or gastrointestinal surgery.
- You are on continuous symptomatic treatment of indigestion or heartburn for 4 or more weeks.
- You continuously suffer from indigestion or heartburn for 4 or more weeks.
- You have jaundice or severe liver disease.
- You are aged over 55 years with new or recently changed symptoms.

Patients should not take omeprazole as a preventative medication.

When taking omeprazole, inflammation in your kidney may occur. Signs and symptoms may include decreased volume of urine or blood in your urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness. You should report such signs to the treating physician.

Other medicines and Losec Control
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 Losec Control can affect the way some medicines work and some medicines can have an effect on Losec Control.

Do not take Losec Control if you are 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 (thrombi)).

Tell your doctor or pharmacist if you are taking any of the following medicines:
- Posaconazole, ketoconazole, itraconazole or voriconazole (used to treat infections caused by a fungus).
- Digoxin (used to treat heart problems)
- 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 Losec Control.
- Medicines that are used to thin your blood, such as warfarin or other vitamin K blockers. Your doctor may need to monitor you when you start or stop taking Losec Control.
- Rifampicin (used to treat tuberculosis)
- Atazanavir (used to treat HIV infection)
- Tacrolimus (in cases of organ transplantation)
- St John's wort (Hypericum perforatum) (used to treat mild depression)
- Cilostazol (used to treat intermittent claudication)
- Saquinavir (used to treat HIV infection)
- Erlotinib (used to treat cancer)
- 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 Losec Control treatment.

Taking Losec Control with food and drink
You can take your tablets with food or on an empty stomach.

Children and adolescents
Do not take Losec Control tablets if you are aged less than 18 years old.

Pregnancy and breast-feeding
Ask your doctor or pharmacist before taking any medicine.

Before taking Losec Control, tell your doctor or pharmacist if you are pregnant or trying to get pregnant. Your doctor will decide whether you can take Losec Control during this time.

Your doctor will decide whether you can take Losec Control if you are breastfeeding.

Driving and using machines
Losec Control is not likely to affect your ability to drive or use any tools or machines. Side effects such as dizziness and visual disturbances may occur (see section 4). If affected, you should not drive or operate machinery.

Important information about some of the ingredients of Losec Control
Losec Control gastro-resistant tablets contain 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 LOSEC CONTROL

Always take Losec Control exactly as described in this leaflet. You should check with your doctor or pharmacist if you are not sure.

The usual dose is one 20 mg tablet once a day for 14 days. Contact your doctor if you are not free from symptoms after this period.

It might be necessary to take the tablets for 2-3 consecutive days to achieve improvement of symptoms.
Usually complete relief of heartburn is achieved within 7 days. If you experience complete relief of symptoms, discontinue treatment.

Taking this medicine
- It is recommended that you take your tablets in the morning, preferably on an empty stomach.
- Swallow your tablets whole with half a glass 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. These micro-pellets contain the active substance omeprazole and are enteric coated which protects them from being broken down during passage through the stomach. The pellets release the active ingredient in the intestine, where it is absorbed by your body to give an effect.

What to do if you have trouble swallowing the tablets
- If you have trouble swallowing the tablets:
    - Break the tablet and disperse it in a spoonful of water (non-fizzy), any acidic fruit juice (e.g. apple, orange or pineapple) or apple sauce.
    - Always stir the mixture just before drinking (the mixture will not be clear). Then drink the mixture straight away or within 30 minutes.
    - 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. **Do not use** milk or fizzy water. The solid pieces contain the medicine - do not chew or crush them.

If you take more Losec Control than you should
If you take more Losec Control than recommended, talk to your doctor or pharmacist straight away or go to the nearest hospital.

If you forget to take Losec Control
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.

4. POSSIBLE SIDE EFFECTS

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

If you notice any of the following rare but serious side effects, stop taking Losec Control 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.

Side effects may occur with certain frequencies, which are defined as follows:

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 the available data

Other side effects include:

Common side effects
- 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 side effects
- Swelling of the feet and ankles.
- Disturbed sleep (insomnia).
- Dizziness, tingling feelings such as "pins and needles", feeling sleepy.
- Spinning feeling (vertigo).
- Changes in blood tests that check how the liver is working.
- Skin rash, lumpy rash (hives) and itchy skin.
- Generally feeling unwell and lacking energy.

Rare side effects
- Blood problems such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely.
- Allergic reactions, sometimes very severe, including swelling of the lips, tongue and throat, fever, wheezing.
- 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).
- Dry mouth.
- 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).
- Severe kidney problems (tubulointerstitial nephritis).
- Increased sweating.

- Inflammation in the gut (leading to diarrhoea).

Very rare side effects
- 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.
- Enlarged breasts in men.
- Hypomagnesaemia (low levels of magnesium in the blood)
- Low levels of calcium in the blood caused by severe hypomagnesaemia
- Low levels of potassium in the blood caused by hypomagnesaemia

Losec Control 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.

Frequency "not known" side effects
- Rash, possibly with pain in the joints.

Do not be concerned by this list of possible side effects. You may not get any of them.

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 Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE LOSEC CONTROL

- Keep out of the sight and reach of children.

- Do not use Losec Control after the expiry date which is stated on the outer and inner pack after EXP. The expiry date refers to the last day of that month.

- Do not store above 25°C.

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

- 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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Losec Control contains

- The active substance is omeprazole. Losec Control gastro-resistant tablets contain omeprazole magnesium corresponding to 20 mg omeprazole.
- The other ingredients are Cellulose microcrystalline, Glycerol monostearate 40-55, Hydroxypropylcellulose, Hypromellose, Macrogol 6000, Magnesium stearate, Methacrylic acid – ethyl acrylate copolymer (1:1)

dispersion 30 percent, Polysorbate 80, Crospovidone (type A), Sodium hydroxide (for pH-adjustment), Sodium stearyl fumarate, sugar spheres (contains sucrose and corn starch), Synthetic paraffin, Talc, Triethyl citrate, Iron oxide reddish-brown (E172), Titanium dioxide (E171)

What Losec Control looks like and contents of the pack

Losec Control 20 mg gastro-resistant tablets are pink with  on one side and 20 mg on the other side.
Pack sizes: Polyamide/Aluminium/PVC blister of 7 or 14 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The MA holder is Bayer Ltd, 1st Floor, The Grange Offices, The Grange, Brewery Road, Stillorgan, Co. Dublin, A94 H2K7, Ireland and the Manufacturer is

SAG Manufacturing, S.L.U, Crta. N-I, km 36, 28750 San Agustin del Guadalix, Madrid, Spain.

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