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Package leaflet: information for the user

Omirel 20 mg capsules

omeprazole

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
This medicine is available without prescription. However, you still need to take Omirel capsules carefully to get the best results from them.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist or doctor 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.

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

1. What Omirel is and what it is used for

The name of your medicine is Omirel 20 mg capsules and 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.

This medicine is used in adults for the short-term treatment of reflux symptoms (for example, heartburn, 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 capsules for 2 to 3 consecutive days to achieve improvement of symptoms.

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 Omirel

Do not take Omirel
- If you are allergic to omeprazole or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to medicines containing other proton pump inhibitors (such as pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- If you are taking a medicine containing nelfinavir (for HIV infection).

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
Tell your doctor or pharmacist before taking this medicine, if:
- You are due to have a specific blood test (Chromogranin A)
- You are due to have an endoscopy or an urea breath test
- Your body does not absorb vitamin B12 (cobalamin) very well

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

Do not take this medicine 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.

Omeprazole may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking this medicine 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 signs of indigestion such as nausea, fullness, bloating, especially after food intake.
- 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.
- You have ever had a skin reaction after treatment with a medicine similar to omeprazole 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 this medicine. 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.
When taking omeprazole, inflammation in your kidneys 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 your doctor.
This medicine may affect the way that your body absorbs vitamin B12, particularly if you need to take it for a long time. Please contact your doctor if you notice any of the following symptoms, which could indicate low levels of vitamin B12:
- Extreme tiredness or lack of energy
- Pins and needles
- Sore or red tongue, mouth ulcers
- Muscle weakness
- Disturbed vision
- Problems with memory, confusion, depression

Do not take omeprazole if you do not have symptoms of reflux (e.g. heartburn or acid regurgitation).

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

Other medicines and Omirel

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 omeprazole can affect the way some medicines work, and some medicines can have an effect on omeprazole.

Do not take this medicine 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)).

Do not take this medicine with other medicines that limit the amount of acid produced in your stomach such as other proton pump inhibitors (e.g. pantoprazole, rabeprazole or esomeprazole) or an H2 antagonist (e.g. ranitidine or famotidine).

You may take this medicine with antacids (e.g. 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, itraconazole, posaconazole or voriconazole (used to treat infections caused by a fungus).
- Clarithromycin (used to treat infections)
- 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 omeprazole
- 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 omeprazole
- 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 omeprazole treatment.

Omirel with food and drink
See section 3 'How to take Omirel'.

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.
Your doctor will decide whether you can take this medicine during this time. There is no evidence that omeprazole has any effect on fertility. Omeprazole is excreted in breast milk but is not likely to influence the child when therapeutic doses are used.
Your doctor will decide whether you can take this medicine if you are breast-feeding.

Driving and using machines
This medicine 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.

Omirel contains sodium
This medicine contains 225 mg sodium (main component of cooking/table salt) in each capsule. This is equivalent to 11.2% of the recommended maximum daily dietary intake of 2g sodium for an adult.

3. How to take Omirel

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The recommended dose is one (20 mg) capsule once a day for up to 14 days. Contact your doctor if you are not free from symptoms after this period.
It might be necessary to take the capsules for 2 to 3 consecutive days to achieve improvement of symptoms.
Do not take more than the recommended dose (one 20 mg capsule a day) even if you don't feel an improvement immediately.
When your reflux symptoms have gone completely you should stop taking this medicine.

Taking this medicine
- It is recommended that you take this medicine in the morning. Take your capsule on an empty stomach, at the same time each day. Empty stomach means at least 30 minutes before food and at least 2 hours after last meal (e.g. in the morning before breakfast). The medicine contains the excipient sodium hydrogen carbonate which protects the active substance omeprazole from being broken down by the acid in the stomach. If the medicine is taken with food the protective effect of sodium hydrogen carbonate is reduced and the medicine may not have its full effect.
- Swallow your capsule whole with half a glass of water. Do not chew or open the capsules because this may stop them from working properly.

If you take more Omirel than you should
If you take more of this medicine than recommended, talk to your doctor or pharmacist straight away.
You may experience symptoms such as diarrhoea, stomach ache, feeling or being sick, dizziness, headache, depression, confusion and apathy (lack of motivation).

If you forget to take Omirel
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 rare (may affect up to 1 in 1 000 people) or very rare (may affect up to 1

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in 10 000 people) but serious side effects, stop taking this medicine 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). (rare)
- 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'. (very rare)
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome). (rare)
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalized exanthematous pustulosis). (rare)
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems. (rare)

Omeprazole 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:

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).
- 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.
- Fractures of the hip, wrist and spine.

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).
- 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.
- Hair loss (alopecia).
- Skin rash on exposure to sunshine.
- Joint pains (arthralgia) or muscle pains (myalgia).
- Severe kidney problems (interstitial nephritis).
- 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.
- Erythema multiforme.
- Muscle weakness.
- Enlarged breasts in men.

Not known (frequency cannot be estimated from the available data)
- Inflammation in the gut (leading to diarrhoea).
- Hypomagnesaemia (deficiency of magnesium in the blood).
- 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5.How to store Omirel

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

Store below 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 protect the environment.

6.Contents of the pack and other information

What Omirel contains
- The active substance is omeprazole. Each hard capsule contains 20 mg of omeprazole.
- The other excipients are sodium hydrogen carbonate (E500ii), sodium starch glycolate (type A), sodium stearyl fumarate (E485) in capsule shell consisting of gelatin (E441), red iron oxide (E172) and titanium dioxide (E171).

What Omirel looks like and contents of the pack
Omirel is a white to off-white powder in a capsule with opaque white body and red cap without printing**.**

The capsules are packed in PVC/PVDC – Alu blisters.

Pack sizes: 7 and 14 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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For information on large print, Braille or audio CD call emc accessibility on 0800 198 5000

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 notice that when you lie down your heartburn gets worse. If you are overweight or smoke you increase the chance of suffering from heartburn.
What can I do to help relieve my symptoms?
- 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.

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