Package leaflet: Information for the patient

Omeprazol (als magnesium) Sandoz® OTC 20 mg, maagsapresistente tabletten

Omeprazole

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 doctor or 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.

What is in this leaflet

1. What [nationally completed name] is and what it is used for

[Nationally completed name] gastro-resistant tablets contain 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.

[Nationally completed name] 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 tablets for 2-3 consecutive days to achieve improvement of symptoms.

2. What you need to know before you take [nationally completed name]

Do not take [Nationally completed name]
- 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 (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- if you are taking a medicine containing nelfinavir (for HIV infection).

Do not take [Nationally completed name] if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking [Nationally completed name].

Warnings and precautions
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 [Nationally completed name] treatment. Stop using [Nationally completed name] 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 [Nationally completed name] 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.

[Nationally completed name] may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking [Nationally completed name] 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.
- You are due to have a specific blood test (Chromogranin A).
- You have ever had a skin reaction after treatment with a medicine similar to [Nationally completed name] 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 [Nationally completed name]. Remember to also mention any other ill-effects like pain in your joints.

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.

Patients should not take omeprazole as a preventative medication.

Other medicines and [nationally completed name]
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 [Nationally completed name] can affect the way some medicines work and some medicines can have an effect on [Nationally completed name].

Do not take [Nationally completed name] 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:
- Ketoconazole, itraconazole, posaconazole 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 [Nationally completed name]
- 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 [Nationally completed name]
- 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 [nationally completed name] treatment.

[Nationally completed name] with food and drink
See section 3.

Pregnancy, breast-feeding and fertility
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.

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 [Nationally completed name] if you are breast-feeding.

Driving and using machines
[Nationally completed name] 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.

[Nationally completed name] gastro-resistant tablets contain glucose 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 [nationally completed name]

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 usual dose is one 20 mg tablet or two 10 mg tablets 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.

[Nationally completed name, 20 mg, gastro-resistant tablets]
The 20 mg tablet can be divided into equal doses

Taking this medicine
- It is recommended that you take your tablets in the morning.
- You can take your tablets with food or 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 substance 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 15 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 [Nationally completed name] than you should
If you take more [Nationally completed name] than recommended, talk to your doctor or pharmacist straight away.

If you forget to take [Nationally completed name]
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, 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 in 10,000 people) but serious side effects, stop taking [Nationally completed name] 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)

Other side effects include:
Common side effects (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).

Uncommon side effects (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.

Rare side effects (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 side effects (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)
- Hypomagnesaemia.
- Inflammation in the gut (leading to diarrhoea).
- Rash, possibly with pain in the joints.

[Nationally completed name] 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.

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 national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

[*For the printed material, please refer to the guidance of the annotated QRD template.]

5. How to store [Nationally completed name]

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

Do not store above 25 °C.

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 [Nationally completed name] contains

The active substance is omeprazole (as omeprazole magnesium).

Each gastro-resistant tablet contains 10 mg omeprazole.
Each gastro-resistant tablet contains 20 mg omeprazole.

The other ingredients are:
Tablet core:
Sucrose, maize starch, glucose, copovidone, povidone, talc, titanium dioxide (E 171), methacrylic acid-ethyl acrylate copolymer (1:1), glycerol monostearate, propylene glycol, stearic acid, polysorbate 80, simeticone, cellulose, microcrystalline, macrogol 6000, crospovidone, silica colloidal anhydrous, magnesium stearate

Tablet coating:
Hypromellose, macrogol 6000, titanium dioxide (E 171), talc, iron oxide, red (E 172), *Only for [Nationally completed name, 10 mg, gastro-resistant tablets]:* iron oxide, yellow (E 172)

What [Nationally completed name]looks like and contents of the pack

[Nationally completed name, 10 mg, gastro-resistant tablets]

Light pink oval film-coated tablet (11.2x5.8 mm).

[Nationally completed name, 20 mg, gastro-resistant tablets]
Pink, oval film-coated tablet with a breaking notch on both sides. The tablet can be divided into equal doses (14.2x7.2 mm).
Pack sizes:
[Nationally completed name] is available in blister packs with 7, 10, 14, 20, 28, 30, 56, 100 gastro-resistant tablets.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant
Vergunninghouder
Sandoz B.V., Veluwezoom 22, 1327 AH, Almere, Nederland
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Duitsland

In het register ingeschreven onder:
RVG 105012

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:
Nederland:
Omeprazol (als magnesium) Sandoz OTC 20 mg, maagsapresistente tabletten

Duitsland
Omeprazol MUT 20 mg magensaftresistente Tabletten

Deze bijsluiter is voor het laatst goedgekeurd in juni 2024