

Package leaflet: Information for the patient

<Invented name>, 20 mg gastro-resistant capsules, hard

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 have 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.

In this leaflet

1. What <Invented name> is and what it is used for
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1. What <Invented name> is and what it is used for

<Invented name> 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.

<Invented 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 capsules for 2-3 consecutive days to achieve improvement of symptoms.

2. What you need to know before you take <Invented name>

Do not take <Invented 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).

Warnings and precautions

Talk to your doctor or pharmacist before taking <Invented name>.

Tell your doctor before taking this medicine, if:

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

Do not take <Invented 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.

<Invented name> may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking <Invented 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.
- If you have ever had a skin reaction after treatment with a medicine similar to <Invented 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 <Invented name>. Remember to also mention any other ill-effects like pain in your joints.

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 <Invented name>

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because <Invented name> can affect the way some medicines work and some medicines can have an effect on <Invented name>.

Do not take <Invented name> 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:

- 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 <Invented 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 <Invented name>.
- rifampicin (used to treat tuberculosis)
- atazanavir (used to treat HIV infection)
- tacrolimus (in cases of organ transplantation)
- erlotinib (used to treat cancer)

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- methotrexate (used to treat cancer). If you are taking high amounts of methotrexate, your doctor may temporarily stop using <Invented name>.
- St John's wort (*Hypericum perforatum*) (used to treat mild depression)
- cilostazol (used to treat intermittent claudication)
- saquinavir (used to treat HIV infection)
- clopidogrel (used to prevent blood clots (thrombi)).

<Invented name> with food and drink

You can take your capsules with food or on an empty stomach.

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 <Invented name> during this time.

Your doctor will decide whether you can take <Invented name> if you are breast-feeding.

Driving and using machines

<Invented 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.

<Invented name> contains sucrose, sodium and eritrosine

Each capsule contains 80.02 mg of 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. Each capsule contains 0.819 mg (0.036 mmol) of sodium, less than 1 mmol sodium (23 mg) per dose, i.e. essentially "sodium-free".

<Invented name> contains eritrosine (E127) - may cause allergic reactions.

3. How to take <Invented 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 recommended dose is one 20 mg capsule 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 capsules for 2-3 consecutive days to achieve improvement of symptoms.

Taking this medicine

- It is recommended that you take your capsules in the morning.
- You can take your capsules with food or on an empty stomach.
- Swallow your capsules whole with half a glass of water. Do not chew or crush the capsules. This is because the capsules contain coated micro granules which stop the medicine from being broken down by the acid in your stomach. It is important not to damage the micro granules. These micro granules contain the active substance omeprazole and are enteric coated which protects them from being broken down during passage through the stomach. The micro granules 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 capsules

If you have trouble swallowing the capsules:

- Open the capsules and swallow the contents directly with half a glass of water or put the contents into a glass of still (non-fizzy) water, any acidic fruit juice (e.g. apple, orange or pineapple) or apple sauce.
Always stir the mixture just before drinking it (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. The solid pieces contain the medicine - do not chew or crush them.

If you take more <Invented name> than you should

If you take more <Invented name> than recommended, talk to your doctor or pharmacist straight away.

If you forget to take <Invented 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 but serious side effects, stop taking <Invented 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).
- 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 below.

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)
- benign polyps in the stomach.

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

- 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
- large intestine inflammation (leading to diarrhoea)
- 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 (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
- 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.

Not known (frequency cannot be estimated from the available data)

- hypomagnesaemia. If you are on <Invented name> -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 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.
- rash, possibly with pain in the joints.

<Invented 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.

Do not be concerned by this list of possible side effects. You may not get any of them. If you get any side effects, talk to your doctor or pharmacist.

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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Invented name>

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

Bottle: Do not store above 30°C. Keep the bottle tightly closed, in order to protect from moisture. Store in the original package.

Blisters: Do not store above 30°C. Store in the original package.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. 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 <Invented name> contains

- The active substance is omeprazole. Each capsule contains gastro-resistant micro granules of 20 mg omeprazole.
- The other ingredients are: sugar spheres (sucrose and maize starch), Povidone K30, Sodium Lauryl Sulphate, Sodium Starch Glycolate (type A), Trisodium phosphate x 12 H₂O, Hypromellose 6 cP, Triethyl citrate, Methacrylic acid-ethyl acrylate Copolymer (1:1), Sodium hydroxide, Titanium dioxide (E171), Talc.
Capsule cap: Eritrosine (E127), Indigo carmine (E132), Titanium dioxide (E171), Water, purified, Gelatin.
Capsule body: Quinoline yellow (E104), Eritrosine (E127), Titanium dioxide (E171), Water, purified, Gelatin.
The printing ink contains: Shellac, Propylene Glycol, Polyvinylpyrrolidone, Sodium hydroxide, Titanium Dioxide (E171).

What <Invented name> look like and contents of the pack

Capsules have an orange body and blue cap and are marked with "O" cap "20" body, containing white-beige micro granules.

<Invented name> is available in HDPE bottles and polypropylene cap with integral silica gel dessicant or OPA/Aluminium/PVC/Aluminium blisters of 5, 7, 14, capsules.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

<To be completed nationally>

Manufacturer

<To be completed nationally>

Teva Pharma S.L.U.

Poligono Industrial Malpica

Calle C, Numero 4

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