Package leaflet: Information for the user

Omeprazol Pensa 10 mg gastro-resistant capsules, hard
Omeprazol Pensa 20 mg gastro-resistant capsules, hard
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 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.

What is in this leaflet
1. What Omeprazol Pensa is and what it is used for
2. What you need to know before you take Omeprazol Pensa
3. How to take Omeprazol Pensa
4. Possible side effects
5. How to store Omeprazol Pensa
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1. What Omeprazol Pensa is and what it is used for

Omeprazol Pensa gastro-resistant capsules 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.

Omeprazol Pensa 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 Omeprazol

Pensa Do not take Omeprazol Pensa
- 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 Omeprazol Pensa if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Omeprazol Pensa.

Warnings and precautions
Do not take Omeprazol Pensa 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.

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 Omeprazol Pensa treatment. Stop using Omeprazol Pensa and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Omeprazol Pensa may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking Omeprazol Pensa 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 Omeprazol Pensa that reduces stomach acid.
- You are due to have a specific blood test (Chromogranin A).

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 Omeprazol Pensa. Remember to also mention any other ill-effects like pain in your joints.

Patients should not take omeprazole as a preventative medication.

Other medicines and Omeprazol Pensa
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 Omeprazol Pensa can affect the way some medicines work and some medicines can have an effect on Omeprazol Pensa.

Do not take Omeprazol Pensa 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 Omeprazol Pensa.
- 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 Omeprazol Pensa.
- 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 treatment with Omeprazol Pensa.

Omeprazol Pensa 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 Omeprazol Pensa if you are breastfeeding.

Driving and using machines
Omeprazol Pensa 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.

Omeprazol Pensa contains sucrose
Omeprazol Pensa gastro-resistant capsules 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.

Omeprazol Pensa contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Omeprazol Pensa

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one 20 mg capsule or two 10 mg capsules 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 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 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 Omeprazol Pensa than you should
If you take more Omeprazol Pensa than recommended, talk to your doctor or pharmacist straight away.

If you forget to take Omeprazol Pensa
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 stop taking Omeprazol Pensa
Do not stop taking Omeprazol Pensa without first talking to your doctor or pharmacist.

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 in 10,000 people) but serious side effects, stop taking Omeprazol Pensa 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).
- 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.
- 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)
- Inflammation in the gut (leading to diarrhoea).
- Hypomagnesaemia
- Rash, possibly with pain in the joints

Omeprazol Pensa 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.

5. How to store Omeprazol Pensa

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 outer and inner pack after EXP. The expiry date refers to the last day of that month.

Blister Aluminium/aluminium: Do not store above 30°C. Store in the original package, in order to protect from moisture.
Blister PVC-PVDC/aluminium: Do not store above 25°C. Store in the original package, in order to protect from moisture.

Plastic jar: This medicinal product does not require any special temperature storage conditions. Keep the jar tightly closed, 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 Omeprazol Pensa contains

- The active substance is omeprazole. Each capsule contains 10mg 20 mg of omeprazole.
- The other ingredients are: *Granules:* sucrose, maize starch, hypromellose, disodium phosphate dihydrate, methacrylic acid - ethyl acrylate copolymer, talc, triethyl citrate, sodium laurilsulfate, polysorbate 80, titanium dioxide (E171). *Capsules:* gelatin, titanium dioxide (E171). *Printing ink:* shellac, black iron oxide (E172).

What Omeprazol Pensa looks like and contents of the pack

Description:
Omeprazol Pensa 10 mg: Opaque white capsules marked with “OM 10”. Contains white to light beige rounded granules.
Size number 4 capsules (length 14.5 mm).

Omeprazol Pensa 20 mg: Opaque white capsules marked with “OM 20”. Contains white to light beige rounded granules.
Size number 3 capsules (length 15.8 mm).

Pack sizes:
To be completed nationally
Omeprazol Pensa 10 mg:
Blister: 56 gastro-resistant capsules.
Plastic jars with screw cap containing desiccant: 100 (2 x50) gastro-resistant capsules.

Omeprazol Pensa 20 mg:
Blister: 14, 28, 56 gastro-resistant capsules.
Plastic jars with screw cap containing desiccant: 28, 32, 56, 100 (2x50), 104 (2x52) gastro-resistant capsules.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Pensa Pharma AB, Norrlandsgatan 10, 111 43 Stockholm, Sweden

Manufacturer

TOWA PHARMACEUTICAL EUROPE, S.L.
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This medicinal product is authorised in the Member States of the EEA under the following names:

Country:	Name of product:
SE, DK, NO	Omeprazol Pensa

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