

Package leaflet: information for the user

omeprazol cinsa 20 mg gastro-resistant hard capsules

Read all of this leaflet carefully before you start taking this medicine, as it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, consult your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you experience any side effects, consult your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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1. What omeprazol cinsa is and what it is used for

Omeprazol cinsa contains the active ingredient omeprazole. It belongs to a group of medicines known as "proton pump inhibitors". These medicines act by reducing the amount of acid produced by the stomach.

Omeprazol cinsa is indicated to treat the following diseases:

In adults:

- "Gastroesophageal reflux disease" (GERD). This condition occurs when stomach acid passes into the oesophagus (the tube that joins the throat to the stomach), causing pain, inflammation and a heartburn.
- Ulcers in the upper part of the intestine (duodenal ulcer) or in the stomach (gastric ulcer).
- Ulcers infected by a bacterium called "*Helicobacter pylori*". If you have this disease, it is likely that your doctor will prescribe antibiotics to treat the infection and allow the ulcer to heal.
- Ulcers caused by some medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). omeprazol cinsa can also be used to prevent the formation of ulcers if you are taking an NSAID.
- Excessive stomach acid produced by a tumour in the pancreas (Zollinger-Ellison syndrome).

In children:

Children over 1 year of age and ≥ 10 kg

- "Gastroesophageal reflux disease" (GERD). This condition occurs when stomach acid passes into the oesophagus (the tube that joins the throat to the stomach), causing pain, inflammation and heartburn. In children, the symptoms of the disease may include the return of the contents of the stomach to the mouth (regurgitation), vomiting and insufficient weight gain.

Children over 4 years of age and adolescents

- Ulcers infected by a bacterium called "*Helicobacter pylori*". If your child suffers from this disease, your doctor may prescribe antibiotics to treat the infection and allow the ulcer to heal.

2. Before you take omeprazol cinfa

Do not take omeprazol cinfa

- 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 that contain proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole or esomeprazole).
- If you are taking a medicine that contains nelfinavir (used to treat HIV infection).

Do not take omeprazol cinfa if you are in any of the abovementioned categories. If you are uncertain, talk to your doctor or pharmacist before taking omeprazol cinfa.

Warnings and precautions

Consult your doctor or pharmacist before starting to take omeprazol cinfa.

Omeprazol cinfa can mask the symptoms of other diseases. Therefore, if you experience any of the following conditions before you start taking omeprazol cinfa or during treatment, consult your doctor immediately:

- You lose weight for no apparent reason and have difficulty swallowing.
- You have stomach pain or indigestion.
- If you have ever had a skin reaction after treatment with a medicine similar to omeprazol cinfa to reduce stomach acidity.
- If you have a skin rash, especially in areas of skin exposed to the sun, consult your doctor as soon as possible, as you may need to discontinue treatment with omeprazol cinfa. Remember to mention any other symptom that you may notice, such as joint pain.
- You start to vomit food or blood.
- Your stools are black (faeces stained with blood).
- If you have severe or persistent diarrhoea, as a slight increase in infectious diarrhoeas has been associated with omeprazole.
- You have severe liver problems.

Before taking this drug, tell your doctor if you are scheduled to have a specific blood test (Chromogranin A).

If you take omeprazol cinfa for a long period of time (more than 1 year) your doctor will probably perform regular check-ups. You should report any new or unusual symptom or circumstances whenever you visit your doctor.

The risk of hip, wrist or spinal column fractures may increase slightly if you are taking proton-pump inhibitors such as omeprazole, especially if you take them for more than one year. Inform your doctor if you have osteoporosis or are taking corticosteroids (which can increase the risk of osteoporosis).

Children

Some children with chronic diseases may require long-term treatment, however this is not recommended. Do not administer this medicine to children under 1 year of age or who weigh <10 kg.

Taking omeprazol cinfa with other medicines

Inform your doctor or pharmacist if you are taking, have recently taken or might have to take any other medicines. This includes non-prescription drugs. This is because omeprazol cinfa can affect the mechanism of action of some medicines, and some medicines can affect omeprazol cinfa.

Do not take omeprazol cinfa if you are taking a medicine that contains **nelfinavir** (used to treat HIV infection).

Inform your doctor or pharmacist if you are taking any of the following medicines:

- Ketoconazole, itraconazole, posaconazole or voriconazole (used to treat fungal infections).
- Digoxin (used to treat heart problems).
- Diazepam (used to treat anxiety, as a muscle relaxant or for epilepsy).

- Phenytoin (used for epilepsy). If you are taking phenytoin, your doctor will need to monitor you when you start or finish your treatment with omeprazol cinfa.
- Drugs used to prevent blood clots like warfarin or other vitamin K antagonists. Your doctor will monitor you when you start or finish your treatment with omeprazol cinfa.
- Rifampicin (used to treat tuberculosis).
- Atazanavir (used to treat HIV infection).
- Tacrolimus (in cases of organ transplant).
- Saint 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 (thrombosis)).
- Erlotinib (used to treat cancer).
- Methotrexate (chemotherapy drug used in high doses to treat cancer) - if you are taking a high dose of methotrexate, your doctor will have to temporarily stop treatment with omeprazol cinfa.

If, in addition to omeprazol cinfa, your doctor has prescribed to you the antibiotics amoxicillin and clarithromycin to treat ulcers caused by infection with *Helicobacter pylori*, it is very important that you inform your doctor about the other medicines you are taking.

Taking omeprazol cinfa with food and drink

You may take your capsules with food or on an empty stomach. See section 3.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, suspect that you might be pregnant or intend to become pregnant, consult your doctor or pharmacist before taking this medicine.

Omeprazole passes into breast milk, but it is unlikely to affect the child when used in therapeutic doses.

Your doctor will decide if you can take omeprazol cinfa if you are breastfeeding.

Driving and using machines

Omeprazol cinfa is unlikely to affect your ability to drive or use machinery or tools. Side effects such as dizziness and visual disturbances may appear (see section 4). If this occurs, you should not drive or use machinery.

Omeprazol cinfa contains sucrose and sodium

This medication contains sucrose. If you have been told by your doctor that you are intolerant to certain sugars, please consult your doctor before taking this medicine.

This medicine contains less than 1 mmol of sodium (23 mg) per dose unit; that is, it is essentially “sodium-free”.

3. How to take omeprazol cinfa

Always take omeprazol cinfa exactly as your doctor has instructed you to. Consult your doctor or pharmacist again if you are not sure.

Your doctor will indicate how many capsules you should take and for how long. This will depend on your condition and age.

The recommended dose is:

Use in adults

Treatment of the symptoms of GERD, such as **heartburn and acid regurgitation:**

- If your doctor finds that you have slight damage to your oesophagus, the recommended dose is 20 mg once a day for 4-8 weeks. Your doctor may prescribe a dose of 40 mg for another 8 weeks if your oesophagus has not yet healed.
- recommended dose once the oesophagus has healed is 10 mg once a day.

- If your oesophagus is not damaged, the recommended dose is 10 mg once a day.

Treatment of **ulcers of the upper part of the intestine** (duodenal ulcer):

- The recommended dose is 20 mg once a day for 2 weeks. Your doctor may prescribe the same dose for another 2 weeks if the ulcer has not yet healed.
- If the ulcer does not fully heal, the dose may be increased to 40 mg once a day for 4 weeks.

Treatment of **stomach ulcers** (gastric ulcer):

- The recommended dose is 20 mg once a day for 4 weeks. Your doctor may prescribe the same dose for another 4 weeks if the ulcer has not yet healed.
- If the ulcer does not fully heal, the dose may be increased to 40 mg once a day for 8 weeks.

Prevention of the recurrence of **stomach and duodenal ulcers**:

- The recommended dose is 10 mg to 20 mg once a day. Your doctor may increase your dose to 40 mg once a day.

Treatment of stomach and duodenal ulcers caused by non-steroidal anti-inflammatory drugs (NSAIDs):

- The recommended dose is 20 mg once a day for 4-8 weeks.

Prevention of stomach and duodenal ulcers during administration of NSAIDs:

- The recommended dose is 20 mg once a day.

Treatment of **ulcers caused by *Helicobacter pylori*** infection and prevention of their recurrence:

- The usual dose is 20 mg of omeprazol cinsa twice a day for a week.
- Your doctor will also instruct you to take two of the following antibiotics: amoxicillin, clarithromycin and metronidazole.

Treatment of excessive stomach acid produced by a **tumour in the pancreas (Zollinger-Ellison syndrome)**:

- The recommended dose is 60 mg a day.
- Your doctor will adjust the dose depending on your needs and will also decide how long you should take this medicine.

Children and adolescents

Treatment of the symptoms of GERD, such as **heartburn and acid regurgitation**

- Children over 1 year of age weighing more than 10 kg can take omeprazol cinsa. The dose for children is based on body weight, and your doctor will determine the correct dose.

Treatment of **ulcers caused by *Helicobacter pylori*** infection and prevention of their recurrence:

- Children over 4 years of age can take omeprazol cinsa. The dose for children is based on body weight, and your doctor will determine the correct dose.
- The doctor will also prescribe for your child two antibiotics, amoxicillin and clarithromycin.

How to take this medicine

- Taking the capsules in the morning is recommended.
- You may take your capsules with food or on an empty stomach.
- Swallow the capsules whole with half a glass of water. Do not chew or crush the capsules, as they contain coated granules that prevent the medicine from breaking down from the action of stomach acid. It is therefore important not to damage the granules.

What to do if you or your child has problems swallowing capsules

- If you or your child has problems swallowing capsules:
 - Open the capsules and swallow the contents directly with half a glass of water, or pour the contents into a glass of still water, an acidic fruit juice (e.g. apple, orange or pineapple) or apple sauce.

- Always shake the mixture just before drinking (the mixture will not be transparent). Then drink the mixture immediately or within 30 minutes.
- To make sure that you have taken all of the medicine, fill the glass of water halfway, swirl it thoroughly and drink all of the water. The solid parts contain the medicine; do not chew or crush them.

If you take more omeprazol cinfa than you should

If you take more omeprazol cinfa than prescribed by your doctor, consult your doctor or pharmacist immediately.

In case of overdose or accidental ingestion, consult your doctor or pharmacist immediately or call the Toxicology Information Service, telephone +34 91 562 04 20, indicating the medicine and quantity ingested.

If you forget to take omeprazol cinfa

If you forget to take a dose, take it as soon you remember. However, if it is almost time for the next dose, skip the forgotten dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking omeprazol cinfa

Do not stop the treatment with omeprazol cinfa without first talking to your doctor or pharmacist. If you have any further questions about 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 will experience them.

If you notice any of the following rare but serious side effects, stop taking omeprazol cinfa and consult your doctor immediately:

- Sudden wheezing (whistling sound when breathing), swelling of the lips, tongue and throat or body, skin rash, fainting, or difficulty swallowing (serious allergic reaction).
- Reddening of the skin with the formation blisters or peeling. Severe blisters and bleeding of the lips, eyes, mouth, nose and genitals may also appear. It could be due to “Stevens-Johnson syndrome” or “toxic epidermal necrolysis”.
- Yellow skin, darkened urine and tiredness, which can be symptoms of liver problems.

Other side effects include:

Common side effects (may affect up to 1 in 10 people):

- Headache.
- Effects on the stomach or the intestine: diarrhoea, stomach ache, constipation and wind (flatulence).
- Nausea or vomiting.
- Benign polyps in the stomach.

Uncommon side effects (may affect up to 1 in 100 people):

- Swollen feet and ankles.
- Sleep disturbances (insomnia).
- Dizziness, tingling sensation, drowsiness.
- Feeling that everything is spinning (vertigo).
- Changes in blood tests for checking liver function.
- Skin rash, welts and itching.
- General feeling of malaise and lack of energy.

Rare side effects (may affect up to 1 in 1,000 people)

- Problems in the blood, such as a reduction in white blood cells or platelets. This can cause weakness or bruising and increase the likelihood of contracting infections.
- Allergic reactions, sometimes very intense, which include swelling of the lips, tongue and throat,

- fever, and wheezing.
- Low concentration of sodium in the blood. This can cause weakness, vomiting and cramps.
- Agitation, confusion or depression.
- Taste alterations.
- Visual impairment, such as blurred vision.
- Sudden sensation of shortness of breath (bronchospasm).
- Dry mouth.
- Inflammation inside the mouth.
- Infection called “thrush”, which can affect the intestine and is caused by a fungus.
- Liver problems, such as jaundice, which can cause yellowing of the skin, dark urine and tiredness.
- Hair loss (alopecia).
- Skin rash with exposure to sunlight.
- Joint pain (arthralgia) or muscle pain (myalgia).
- Serious kidney problems (interstitial nephritis).
- Increased sweating.

Very rare side effects (may affect up to 1 in 10,000 people):

- Alterations to blood count, such as agranulocytosis (lack of white blood cells).
- Aggressiveness.
- Seeing, feeling or hearing things that do not exist (hallucinations).
- Severe liver problems that cause liver failure and inflammation of the brain.
- Sudden appearance of a severe skin rash, formation of blisters or peeling of the skin. May be accompanied by a high fever and joint aches (erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Muscle weakness.
- Increased breast size in males.

Frequency unknown (frequency cannot be estimated from the available data).

- Rash, possibly with joint pain
- Inflammation in the intestine (which causes diarrhoea).
- If you are taking omeprazol cinsa for longer than three months, the magnesium levels in your blood may go down. Low magnesium levels may manifest as tiredness, involuntary muscle spasms, disorientation, seizures, dizziness or increased heart rate. If you have any of these symptoms, inform your doctor immediately. Low magnesium levels may also cause the potassium and calcium levels in your blood to drop. Your doctor may decide to perform regular blood tests to monitor your magnesium levels.

On rare occasions, omeprazol cinsa may affect white blood cells and trigger an immunodeficiency. If you suffer from an infection with symptoms, such as a fever with a very poor overall condition, or fever with symptoms of a local infection, such as pain in your neck, throat or mouth or difficulty urinating, you should consult your doctor as soon as possible to have a blood test and be able to rule out a lack of white blood cells (agranulocytosis). It is important at that moment for you to provide information about the medicine you are taking.

Reporting of side effects

If you experience any type of side effect, consult your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Spanish Pharmacovigilance System for Medicines for Human Use: www.notificaram.es. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store omeprazol cinsa

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

Blister: This medicine product does not require any special storage conditions.

Bottle: Do not store above 25°C. Keep the bottle tightly closed to protect it from moisture. Expires three

months after opening.

Do not use this medicine after the expiry date stated on the carton, on the label of the bottle, or on the blister after “EXP”. The expiry date refers to the last day of the indicated month.

Do not dispose of medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What omeprazol cinfa contains

- The active substance is omeprazole.
- The other ingredients (excipients) are:
 - Capsule contents: sugar spheres (sucrose and corn starch), sodium lauryl sulphate, anhydrous disodium hydrogen phosphate, mannitol (E-421), hypromellose (E-464), macrogol 6000, talc, polysorbate 80, titanium dioxide (E-171), copolymer of methacrylic acid and ethyl acrylate.
 - Hard gelatine capsule: The gelatine capsule is made of gelatine, water, quinoline yellow (E-104) and titanium dioxide (E-171).

What the product looks like and contents of the pack

Omeprazol cinfa is available in the form of hard yellow gelatine capsules containing 20 mg of omeprazole.

Aluminium/Aluminium blister pack: with 14, 28 and 56 capsules.

Marketing authorisation holder and manufacturer:

Laboratorios Cinfa, S.A.
C/ Olaz-Chipi, 10 - Polígono Industrial Areta
31620 Huarte - Pamplona (Navarre)-Spain

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Detailed information on this medicine is available on the website of the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS - Spanish Medicines Agency) <http://www.aemps.gob.es/>.