

PACKAGE LEAFLET: Information for the user

ULCOZOL

Gastro-resistant hard capsules – 20 mg

(Omeprazole)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects bothers you, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT ULCOZOL IS AND WHAT IT IS USED FOR?

Ulcozol capsules contain the active substance omeprazole. Omeprazole belongs to a group of medicines called proton pump inhibitors. Proton pump inhibitors, like omeprazole, reduce the amount of acid produced in the stomach.

Ulcozol is used for the treatment of the following diseases:

- acid reflux from stomach to oesophag, which causes pain, inflammation and burn (reflux oesophagitis and gastrooesophageal reflux disease)
- ulcers in the upper part of intestine (duodenal ulcers) or in stomach (gastric ulcers)
- if you have ever had NSAID (non-steroidal anti-inflammatory drug) related ulcers, and you

should continue taking NSAID, omeprazole may either treat ulcer or prevent it

- ulcers caused by infections from a bacterium called *Helicobacter pylori*
- excessive acidity in stomach which is caused by a syndrome called Zollinger-Ellison.

2. WHAT YOU SHOULD KNOW BEFORE YOU TAKE ULCOZOL?

Ulcozol should not be taken:

- if you are hypersensitive (allergic) to omeprazole, or any of the excipients of Ulcozol
- if you are hypersensitive (allergic) to medicines containing other proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole)
- if you are taking clarithromycin and have impaired liver function
- if you are taking atazanavir or nelfinavir (for the treatment of HIV infection).

Take special care with Ulcozol

Inform your doctor or pharmacist:

- if you have been taking omeprazole or other proton pump inhibitors for a long time, it means for longer than 1 year; in this case or if you are going to take Ulcozol for a long time (longer than 1 year), your doctor should check you regularly; in every appointment with your doctor, you should tell him about all the new symptoms and unusual circumstances;
- if you have any of the following symptoms or had them before: unintentional weight loss, repeated vomiting or vomiting with blood or dark stool; in these circumstances, your doctor may perform additional checks, such as endoscopy or colonoscopy to diagnose your condition and / or to exclude a malignant disease;
- if you are elderly or complications have happened to you before (e.g., bleeding or ulcers) from nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen;
- if meanwhile you are taking NSAIDs; your doctor may advise you to discontinue it;
- if you have or have ever had problems with liver or kidneys; your doctor may check the function of these organs through your blood tests, especially if you have to take Ulcozol for a long time;
- if during treatment with omeprazole you have diarrhea; omeprazole leads to a slight increase in diarrhea caused by bacteria;
- if you are due to have a specific blood test (Chromogranin A);

- if you have ever had a skin reaction after treatment with a medicine similar to Ulcozol 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 Ulcozol. 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.

Severe hypomagnesaemia symptoms have appeared in patients who have been taking omeprazole for three months or for one year. If omeprazole is expected to be used for a prolonged time, or used concomitantly with digoxin or other drugs that may cause hypomagnesaemia (e.g., diuretics), your doctor should check before and periodically during treatment the magnesium levels and take them in consideration.

Proton pump inhibitors, mainly when taken in high doses and for a long time (for more than one year), may increase moderately the risk for hip, wrist or spinal fracture, mainly in elderly or those with other risk factors. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

If your doctor has prescribed omeprazole along with other drugs for the treatment of infection from *Helicobacter pylori* (antibiotics) or has given it together with antiinflammatory drugs for the treatment of pain or some rheumatic disease, read also carefully the leaflet of these drugs.

Children

Omeprazole should not be given to children under 2 years of age.

Taking Ulcozol with other medicines

Inform your doctor or pharmacist if you are taking / using or have recently taken / used any other medicines, including medicines obtained without a prescription. Especially, inform your doctor if you are taking one of the following drugs:

- atazanavir, nelfinavir or saquinavir (drugs used to treat HIV infection)
- ketoconazole, itraconazole, posaconazole, voriconazole or clarithromycin (for treatment of some infections)
- diazepam or other benzodiazepines (sedative or muscle relaxant drugs)
- phenytoin (drug for treatment of epilepsy)
- warfarin (for blood thinning)
- citalopram, imipramine, clomipramine (drugs for treatment of depression)
- disulfiram (drug for treatment of alcoholism)
- digoxin (cardiac drug)
- vitamin B12
- St. John's wort (*Hypericum perforatum*)
- erlotinib (used to treat cancer)
- cilostazol
- clopidogrel (used to prevent blood clots)
- methotrexate (a chemotherapy medicine)
- tacrolimus or cyclosporine (to suppress immune system).

Taking Ulcozol with food and drinks

You can take the capsules at any time of the day before meals or on an empty stomach.

Pregnancy and breastfeeding

Talk to your doctor or pharmacist before taking any drug.

Information about the use of omeprazole during pregnancy is limited. Therefore, you should talk to your doctor before you take Ulcozol during pregnancy.

Omeprazole passes into breast milk, but it is not known if the drug has any effect on the baby. Therefore, you should talk to your doctor before you take Ulcozol during breastfeeding.

Driving and using machines

Ulcozol does not have any known effect on the ability to drive or use machines. However, common side effects of omeprazole may appear such as: headache, fatigue, dizziness and visual and hearing disturbances, which in certain circumstances may impair the ability to drive or use machines.

Important information about some of the excipients of Ulcozol

This medicine contains sucrose and lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE ULCOZOL

Always take Ulcozol as your doctor has instructed you. Ask your doctor or pharmacist if you are not sure.

Method of administration

Ulcozol may be taken by adults and children over 2 years. You can take the capsules at any time of the day before meals or on an empty stomach.

Capsules should be swallowed whole. They should not be chewed or broken to pieces.

Unless otherwise prescribed by the doctor, the usual dose is:

Burns in the oesophagus from stomach acid reflux (reflux oesophagitis)

For adults the usual dose is once a day 20 to 40 mg omeprazole for 4 to 8 weeks. Depending on your response to treatment, your doctor may advise you to take the capsules for a longer time or increase the dose. In order for the symptoms not to be returned, the doctor may also recommend you to continue taking 20 mg omeprazole or reduce the dose to 10 mg.

In children with reflux oesophagitis, omeprazole dose depends on body weight (10 mg / day in weights 10 to 20 kg, 20 mg / day in weights over 20 kg), and treatment should be done for 4-12

weeks. If children can not take the capsules, they can be opened, the contents can be mixed with fruit juice or yogurt and then swallowed.

Prevention of reflux oesophagitis return

The usual dose is 10 to 20 mg omeprazole.

Burns due to gastroesophageal reflux disease

The usual dose is once a day 10 to 20 mg omeprazole for 2 to 4 weeks. Depending on your response to treatment, your doctor may advise you to take the capsules for a longer time or increase the dose.

Treatment and prevention of recurrence of gastric and duodenal ulcers

Treatment: The usual dose is 20 mg omeprazole once daily. The doctor will decide how long you will take the capsules. Normally, the duration of treatment for duodenal ulcer is 2-4 weeks and for gastric ulcer 4-8 weeks. Depending on your response to treatment, it may be necessary to increase the dose. If symptoms reappear, the doctor may increase the dose accordingly.

To prevent gastric and duodenal ulcers from coming back: The usual dose is 10 mg or 20 mg once a day. Your doctor may increase the dose to 40 mg once a day.

Treatment and prevention of gastric and duodenal ulcers and also associated symptoms caused by NSAIDs

If you had problems with ulcers, but needed to take a NSAID, the recommended dose is 20 mg omeprazole once daily. The doctor will tell you how long you should take the capsules. For an acute ulcer, the treatment time is usually between 4 and 8 weeks. If you take omeprazole for the prevention of ulcers, treatment continues for as long as the doctor instructs you.

The treatment of ulcers caused by infection by the bacterium *Helicobacter pylori*

The usual dose is 20 mg omeprazole twice daily. The doctor will tell you which combined therapy to use.

The following combinations with antibiotics are recommended:

omeprazole 20 mg + amoxicillin 1,000 mg + clarithromycin 500 mg

or

omeprazole 20 mg + clarithromycin 250 mg + metronidazole 400-500 mg,
all taken twice daily.

The normal duration of treatment is 1 week. Follow the instructions precisely for how to take the drug and ask your doctor if you are not sure.

Treatment of excessive stomach acidity caused by Zollinger-Ellison syndrome

The usual initial dose is 60 mg omeprazole once daily. If the dose is more than 80 mg daily, half of the dose should be taken in the morning and half in the evening. Your doctor will tell you how many capsules to take each time.

If you take more Ulcozol than you should

Immediately inform your doctor or pharmacist or go to the emergency of the nearest hospital.

If you forget to take Ulcozol

Take the capsule as soon as you remember, unless it is time for the subsequent dose. Do not take a double dose to make up the missed dose.

If you stop taking Ulcozol

Do not stop taking Ulcozol without first talking to your doctor, otherwise you risk the success of the treatment.

If you have further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Ulcozol can cause side effects, although not everybody gets them.

Inform your doctor or pharmacist if any of the side effects bothers you or if you notice any side effects not listed in this leaflet.

If you get any of the side effects mentioned below, immediately stop taking this drug and inform the doctor or go to the emergency of the nearest hospital:

- severe allergic reaction (angioedema), means swelling of face, lips, tongue or neck, or difficulty in respiration or swallowing
- strong reddening and formation of blisters on the skin (Stevens-Johnson syndrome).

The serious side effects mentioned above, which require medical treatment, are rare.

Common side effects (less than 1 out of 10, but more than 1 out of 100 users)

- Headache, dizziness, fatigue (somnolence) or sleep disorders
- Diarrhoea, constipation, nausea or vomiting, benign polyps in the stomach, flatulence and stomach pain.

Uncommon side effects (less than 1 out of 100, but more than 1 out of 1,000 users)

- Lethargy and a general condition which is not good
- Increased liver enzymes values (yellowing of the eyes or skin)
- Blurred vision and disorders of the ability to see, sensitivity to light, taste disorders, tinnitus, vertigo
- Blisters on the skin or ripped off skin, rash, itching on the skin, hair loss, increased sweating, swelling of the legs.

Rare side effects (less than 1 out of 1,000, but more than 1 out of 10,000 users)

- Anemia in children
- Brownish-black discoloration of the tongue if you are taking concomitantly the antibiotic clarithromycin, swelling of the glands of the stomach; both of these symptoms have appeared after discontinuation of treatment with capsules
- Weakness and muscular pain, joint pain

- Paresthesia and dizziness
- Confusion and hallucinations in seriously ill patients or in the elderly.

Very rare side effects (less than 1 out of 10,000 users or sporadic cases with unknown frequency)

- Dry mouth or inflammation of the mouth (stomatitis)
- Mycotic infections (candidiasis)
- Inflammation of the pancreas (pancreatitis) and inflammation of the liver (with or without jaundice, means yellowing of the skin and eyes) (hepatitis), hepatic failure and brain damage in patients with existing severe hepatic disease
- Changes in the blood formula, which can cause bruising or increase the chance for infections (thrombocytopenia, leukopenia, pancitopenia, agranulocytosis)
- Severe skin rash and mucous membranes, accompanied by blisters, with fever and weakness (Stevens-Johnson syndrome or toxic epidermal necrolysis)
- Inflammation of the kidneys, which can cause swelling of the joints and high blood pressure (nephritis)
- Excessive irritation and depression in patients severely ill or in the elderly
- Urticaria, increased temperature, severe allergic reaction with swelling of the face and neck, and breathing with gasping or whistling (anaphylaxis), severe allergic reaction which causes difficulty in breathing or dizziness, fever
- Low salt levels in blood, which can cause: confusion, fatigue, muscle tremors, convulsions or loss of consciousness (hyponatremia)
- Enlargement of breast in males (gynecomastia)
- Allergic inflammation of the blood vessels that can damage the circulation (vasculitis)
- Rash, possibly with pain in the joints (unknown frequency).

5. HOW TO STORE ULCOZOL

Store below 30°C.

Store in the original package in order to protect the content from moisture.

Keep out of the reach and sight of children.

You should not use Ulcozol after the expiry date, which is stated on the package.

6. FURTHER INFORMATION

What Ulcozol 20 mg gastro-resistant hard capsules contain

The active substance is omeprazole. Each capsule contains gastro-resistant granules with 20 mg omeprazole.

The excipients are:

Pellets content: sugar spheres, lactose, hypromellose, hydroxypropyl cellulose, sodium lauryl sulphate, sodium phosphate dibasic, hypromellose phthalate, diethyl phthalate.

Capsule shell: gelatin, red iron oxide, yellow iron oxide, indigotine.

Contents of the pack

Box with 30 capsules.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

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