

**Package leaflet: Information for the patient****Omeprazol Slavia 20 mg gastro-resistant capsules**  
Omeprazole

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

- 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 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.

**What is in this leaflet:**

1. What Omeprazol Slavia is and what it is used for
2. What you need to know before you take Omeprazol Slavia
3. How to take Omeprazol Slavia
4. Possible side effects
5. How to store Omeprazol Slavia
6. Contents of the pack and other information

**1. What Omeprazol Slavia is and what it is used for**

Omeprazol Slavia contains the active substance omeprazole. It belongs to a class of medicines called “proton pump inhibitors”. They work by reducing the amount of acid your stomach produces.

Omeprazol Slavia is used for the treatment of the following conditions:

In adults:

- “Gastro-oesophageal reflux disease” (GORD). In this disease, stomach acid flows back up into the esophagus (the tube that connects the throat to the stomach), causing pain, inflammation and a burning sensation in the chest (pyrosis);
- Ulcers in the upper part of the intestine (duodenal ulcer) or in the stomach (gastric ulcer);
- Ulcers infected with a bacteria called “*Helicobacter pylori*.” If you have this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal;
- Ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs);
- Omeprazole can also be used to prevent ulcers from forming when you are taking NSAIDs;
- Too much acid in the stomach caused by a tumor in the pancreas (Zollinger-Ellison syndrome).

In children:

*Children over 1 year of age and body weight  $\geq 10$  kg*

- “Gastro-oesophageal reflux disease” (GORD). In this disease, stomach acid flows back up into the esophagus (the tube that connects the throat to the stomach), causing pain, inflammation and a burning sensation in the chest (pyrosis).

Among the symptoms of this disorder, children may also experience the return of stomach contents into the mouth (regurgitation), vomiting and poor weight gain.

*Children and adolescents over 4 years of age*

- Ulcers infected with a bacteria called “*Helicobacter pylori*.” If your child has this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.

## **2. What you need to know before you take Omeprazol Slavia**

### **Do not take Omeprazol Slavia:**

- If you are allergic to omeprazole or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to other proton pump inhibitor medicines (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- If you are taking a medicine containing nelfinavir (used for HIV infections).

**Do not take Omeprazol Slavia if any of the above situations apply to you.**

**If you are not sure, talk to your doctor or pharmacist before taking this medicine.**

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Omeprazol Slavia.

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

Omeprazol Slavia may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you take Omeprazol Slavia or while you are taking this medicine, tell your doctor immediately:

- You lose a lot of weight for no reason and have trouble swallowing.
- You get stomach pain or indigestion.
- You begin to vomit food or blood.
- You pass black stools (bloody stools).
- You experience severe or persistent diarrhoea, as omeprazole has been associated with a small increase in infectious diarrhoea.
- You have severe liver problems.
- If you have ever had a skin reaction following treatment with a medicine that decreases the amount of stomach acid, a medicine similar to Omeprazol Slavia.
- If you are going to have a specific blood test (Chromogranin A).

If you are taking Omeprazol Slavia on a long-term basis (longer than 1 year) your doctor will probably monitor you at regular intervals. You should tell your doctor about any symptoms and about new and exceptional conditions.

Taking proton pump inhibitors such as Omeprazol Slavia, especially over a period of more than one year, may slightly increase the risk of fractures in the hip, wrist and spine. Please tell your doctor if you have osteoporosis or if you are taking corticosteroids (which may increase the risk of osteoporosis).

If you develop a skin rash, especially in areas exposed to the sun, contact your doctor immediately, as you may need to stop taking Omeprazol Slavia. Don't forget to tell your doctor about other symptoms that occur during treatment with Omeprazol Slavia, such as joint pain.

When taking omeprazole, inflammation of the kidneys may occur. Signs and symptoms may include decreased urine volume or blood in the urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness. You should report such signs to your doctor.

This medicine may affect your body's absorption of Vitamin B12, especially if you have to take it for a long time. Tell your doctor if you have any of the following symptoms, which may indicate a low level of Vitamin B12:

- Extreme tiredness or lack of energy;
- Tingling and prickling;
- Inflamed or red tongue, mouth ulcers;
- Muscle weakness;
- Blurred vision;
- Memory problems, confusion, depression.

### **Children**

Some children with chronic illnesses may require long-term treatment, although this is not recommended. Do not give this medicine to children under 1 year of age or <10 kg.

### **Other medicines and Omeprazol Slavia**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription. This is necessary because Omeprazol Slavia can affect the way some medicines work and some medicines can have an influence on Omeprazol Slavia.

Do not take Omeprazol Slavia 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, posaconazole or voriconazole (used to treat fungal infections);
- 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 Slavia;
- Medicines used to thin the blood, such as warfarin or other vitamin K blockers. You may need monitoring by your doctor when you start or stop taking Omeprazol Slavia;
- 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);
- Clopidogrel (used to prevent blood clots (thrombi));
- 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 Slavia.

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin, as well as Omeprazol Slavia for the treatment of ulcers caused by *Helicobacter pylori* infection, it is very important that you inform your doctor about any other medicines you are taking.

#### **Omeprazol Slavia with food, drink and alcohol**

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

#### **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 milk, but is unlikely to have any influence on the child when therapeutic doses are used.

Your doctor will decide if you can take Omeprazol Slavia while breastfeeding.

#### **Driving and using machines**

Omeprazol Slavia is unlikely to affect your ability to drive or use machines.

Side effects such as dizziness and visual disturbances may occur (see section 4). You should not drive or use machines if you experience these side effects.

#### **Omeprazol Slavia contains sugar**

If your doctor has told you that you have an intolerance to some sugars, contact him before taking this medicine.

**Omeprazol Slavia contains methyl p-hydroxybenzoate (E 218) and propyl p-hydroxybenzoate (E 216).** May cause allergic reactions (possibly delayed).

### **3. How to take Omeprazol Slavia**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how many capsules to take and for how long. This depends on your condition and how old you are.

The usual doses are given below.

#### **Adults:**

To treat GORD symptoms such as **pyrosis and acid regurgitation:**

- If your doctor has found that your esophagus is slightly affected, the recommended dose is 20 mg once a day for 4-8 weeks. If the esophagus has not healed, your doctor may tell you to take a dose of 40 mg for another 8 weeks.
- After the esophagus has healed, the recommended dose is 10 mg once a day.
- If the esophagus has not been affected, the usual dose is 10 mg once a day.

To treat ulcers in the **upper part of the intestine** (duodenal ulcer):

- The recommended dose is 20 mg once a day for 2 weeks. If the ulcer has not healed, your doctor may tell you to take the same dose for another 2 weeks.
- If the ulcer does not heal completely, the dose may be increased to 40 mg once a day for 4 weeks.

To treat **stomach ulcers** (gastric ulcer):

- The recommended dose is 20 mg once a day for 4 weeks. If the ulcer has not healed, your doctor may tell you to take the same dose for another 4 weeks.
- If the ulcer does not heal completely, the dose may be increased to 40 mg once a day for 8 weeks.

To **prevent** the recurrence of **duodenal and gastric ulcers**:

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

To treat duodenal and gastric **ulcers caused by NSAIDs** (Non-Steroidal Anti-Inflammatory Drugs):

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

To prevent **duodenal and gastric ulcers**, if you are taking **NSAIDs**:

- The recommended dose is 20 mg once a day.

To treat **ulcers caused by *Helicobacter pylori*** infection and prevent them from coming back:

- The recommended dose is 20 mg Omeprazol Slavia twice a day for one week.
- Your doctor will also tell you to take two antibiotics among amoxicillin, clarithromycin and metronidazole.

To treat too much acid in the stomach caused by a **tumor in the pancreas (Zollinger-Ellison syndrome)**:

- The recommended dose is 60 mg per day.
- Your doctor will adjust the dose depending on your needs and will also decide how long you need to take the medicine for.

### **Use in children and adolescents:**

To treat GORD symptoms such as **pyrosis and acid regurgitation**:

- Children over 1 year of age and with a body weight of more than 10 kg can take Omeprazol Slavia. The dose for children will be determined based on the child's weight. Your doctor will decide the correct dose.

To treat **ulcers caused by *Helicobacter pylori*** infection and prevent them from coming back:

- Children over 4 years of age can take omeprazole. The dose for children will be determined based on the child's weight. Your doctor will decide the correct dose.
- Your doctor will also prescribe two antibiotics called amoxicillin and clarithromycin for your child.

### **Taking this medicine**

- It is recommended to take the capsules in the morning.
- You can take the capsules on an empty stomach or with food.
- Swallow the capsules whole with half a glass of water. Do not chew or crush the capsules. This is because the capsules contain coated microgranules which stop the medicine from being broken down by the acidity in your stomach. It is important not to damage the microgranules.

What to do if you or your child has trouble swallowing 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-carbonated) 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 immediately or within 30 minutes.

- To make sure 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 carbonated water. The solid pieces contain the medicine - do not chew or crush them.

**If you take more Omeprazol Slavia than you should**

If you take more Omeprazol Slavia than your doctor has prescribed, contact your doctor or pharmacist immediately.

**If you forget to take Omeprazol Slavia**

If you forget to take a dose, take it as soon as you remember. 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 Slavia**

Do not stop taking Omeprazol Slavia 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 Slavia and contact your doctor immediately:**

- Sudden wheezing, swelling of the lips, tongue, throat or body, rash, fainting or difficulty in swallowing (severe allergic reaction) (rare side effects).
- Redness of the skin with blisters or peeling. Severe blisters and bleeding of the lips, eyes, nose and genitals may also occur. This may be “Stevens-Johnson syndrome” or “toxic epidermal necrolysis” (very rare side effects).
- Widespread skin rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome) (rare side effects).
- A widespread red, scaly rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the start of treatment (acute generalised exanthematous pustulosis) (rare side effects).
- Yellow skin, dark urine and fatigue, which may be symptoms of liver problems (rare side effects).

Other side effects include:

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

- Headache;
- Effects on your stomach or intestines: diarrhea, stomach pain, constipation, gas (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 (edema);
- Sleep disorders (insomnia);
- Dizziness, tingling sensation such as “pins and needles”, feeling sleepy;
- Spinning feeling (vertigo);
- Changes in liver enzyme levels that show how the liver is working;
- Skin rash, lumpy rash (urticaria) and itchy skin;

- Generally feeling unwell and lacking energy.

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

- Blood changes, such as a decrease in the number of white blood cells (leukopenia) or platelets (thrombocytopenia). This may cause weakness, bruising or an increased risk of infections;
- 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;
- Inflammation of the inside of the mouth;
- Infection called “candidiasis” which affects the intestines and is caused by a fungus;
- 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 (tubulointerstitial nephritis) (with possible progression to kidney failure);
- Increased sweating;
- Sudden onset of a severe skin rash or blisters or skin peeling. These may be associated with high fever and joint pain (erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis);
- Acute generalized exanthematous pustulosis (AGEP);
- Drug reaction with eosinophilia and systemic symptoms (DRESS).

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

- Changes in blood count including decreased white blood cell count (agranulocytosis) and red blood cell count;
- Aggressive behavior;
- Hearing, feeling or seeing things that are not there (hallucinations);
- Severe liver problems leading to liver failure and brain damage;
- Muscle weakness;
- Enlarged breasts in men (gynecomastia).

**Not known side effects, frequency cannot be estimated from the available data:**

- Inflammation of the intestine (causing diarrhea).
- Hypomagnesemia. If you are on omeprazole for more than three months, it is possible that the levels of magnesium in your blood may decrease. Low magnesium levels can be felt as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, very fast heartbeat. If you get any of these symptoms, please tell your doctor immediately. Low magnesium levels can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform periodic blood tests to monitor your magnesium levels.
- Skin rash, possibly with joint pain.

In very rare cases, Omeprazol Slavia may affect the white blood cells, leading to immune deficiency. If you have an infection with symptoms such as fever with a **severely** altered general condition or fever with symptoms of local infection such as pain in the throat, pharynx 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 at:  
National Agency for Medicines and Medical Devices of Romania

Aviator Sănătescu no. 48, district 1

Bucharest 011478-RO

e-mail: [adr@anm.ro](mailto:adr@anm.ro)

Website: [www.anm.ro](http://www.anm.ro)

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

### **5. How to store Omeprazol Slavia**

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

Store below 25°C, in the original package, protected from moisture.

Do not use this medicine after the expiry date which is stated on the package after EXP. The expiry date refers to the last day of that month.

### **EXPIRED AND/OR UNUSED MEDICINES MUST BE RETURNED TO PUBLIC OR PRIVATE HOSPITALS.**

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 Slavia contains**

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

The other ingredients are:

#### Capsule contents:

Mannitol (E421), starch, sucrose (sugar), dextrin, sodium lauryl sulfate, disodium phosphate anhydrous, sodium carbonate anhydrous, calcium carbonate, hypromellose 15 cPs, methacrylic acid copolymer type C, diethyl phthalate, talc, titanium dioxide (E171).

#### Capsule shell:

*Cap:* titanium dioxide (E171), brilliant blue FCF (E133), erythrosine (E127), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), gelatin;

*Body:* titanium dioxide (E171), quinoline yellow (E104), green S (E142), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), gelatin.

#### **What Omeprazol Slavia looks like and contents of the pack**

Omeprazole is presented as hard gelatin capsules, size no. 2, with an opaque blue cap and an opaque green body, containing white or almost white spherical microgranules.

Box with 3 PVC/Al blisters of 10 gastro-resistant capsules each

Box with 3 Al/Al blisters of 10 gastro-resistant capsules each

**Marketing Authorisation Holder and Manufacturer**

Slavia Pharm S.R.L.  
Theodor Pallady Blvd, no. 44C,  
3<sup>rd</sup> District, postal code 032266, Bucharest,  
Romania

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**Other sources of information**

Detailed information on this medicine is available on the website of the National Agency for Medicines and Medical Devices of Romania <http://www.anm.ro/>