

Package leaflet: information for the patient**Loperamid Slavia 2 mg capsules**

Loperamide hydrochloride

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

Always use this medicine as directed in this leaflet or as directed by your physician or your pharmacist.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need additional information or advice.
- If you get any adverse reactions, talk to your physician or your pharmacist. This includes any possible adverse reactions not listed in this leaflet. See section 4.
- If after 2 weeks you do not feel better or if you feel worse, you should see a physician.

What is in this leaflet

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1. What Loperamid Slavia is and what it is used for

Loperamid Slavia contains loperamide hydrochloride, which belongs to a group of medicines called peristalsis inhibitors, antipropulsives. Loperamid Slavia is used for the treatment of a sudden (acute) episode of diarrhea or for long-lasting (chronic) diarrhea.

In case of diarrhea, Loperamid Slavia makes stools more consistent and less frequent.

If after 2 weeks you do not feel better or if you feel worse, you should see a physician.

2. What you need to know before you use Loperamid Slavia**Do not use Loperamid Slavia:**

- if you are allergic to loperamide hydrochloride or to any other component of this medicine (listed in section 6);
- if you have a high fever and bloody stools;
- if you suffer from an inflammatory disease in the region of the lower abdomen (for example pseudomembranous enterocolitis, bacterial enterocolitis or ulcerative colitis, ulcerative rectocolitis, consecutive to ulcer or antibiotic treatment);
- if the slowing down of bowel activity must be avoided, due to the possible risk of significant complications, including: ileus, megacolon and toxic megacolon;
- if you have constipation, abdominal distension or low bowel mobility.

If you have any questions, ask your physician or pharmacist.

Warnings and precautions

Talk to your physician, pharmacist or nurse before taking Loperamid Slavia.

Only take this medicine for the approved indication (see section 1) and never take more than recommended (see section 3). In patients who have taken too much loperamide, the active substance of Loperamid Slavia, serious heart problems (symptoms including fast or irregular heartbeat) have been reported.

- Although Loperamid Slavia stops diarrhea, it will not treat its cause. Whenever possible, the cause of diarrhea must also be treated.
- When you have diarrhea, you lose a lot of fluids. That's why you need to replace lost fluids (drink many liquids). This is especially important in children. The pharmacist will be able to give you a special powder containing sugar and mineral salts. When added to water, it will replace the salts that you lost during a diarrheal episode. The solution is particularly indicated for children.
- In case of a sudden (acute) attack of diarrhea, Loperamid Slavia will usually stop the symptoms within 48 hours. If things do not happen like this, stop the treatment and contact your physician.
- If your physician advises you to avoid treatments that slow down bowel movement, don't take Loperamid Slavia. Such a case can be constipation or bloating.
- Tell your physician if you have liver problems; you may need careful medical attention while taking Loperamid Slavia.
- If you have AIDS and are being treated with Loperamid Slavia for diarrhea, if you have any sign of bloating or bulging of the abdomen, stop treatment with Loperamid Slavia immediately and inform your physician.

Loperamid Slavia with other medicines

Tell your physician or pharmacist if you are taking, have recently taken or might take any other medicines.

Concomitant use of Loperamid Slavia and sedative drugs, such as benzodiazepines or associated drugs, increases the risk of drowsiness, difficulty breathing (respiratory depression), coma and can be life-threatening. For this reason, concomitant use should only be considered when other treatment options are not possible.

However, if your physician prescribes Loperamid Slavia together with sedatives, the dose and duration of concomitant treatment should be limited by your physician.

Please tell your physician about all sedative medications you are taking and follow your physician's recommendations carefully. It may be helpful to inform friends or relatives about the signs and symptoms mentioned above. Address your physician if you have such symptoms.

In particular, inform your physician if you are using drugs that slow down the activity of the stomach and intestines (eg anticholinergics), because they can cause a strong effect of the drug.

Tell your physician or pharmacist if you are taking the following medicines:

- Quinidine (used for irregular heart rhythm or malaria)
- Ritonavir (used in the treatment of HIV)
- Ketoconazole or itraconazole (used in fungal infections)
- Gemfibrozil (used to treat high cholesterol levels)
- Desmopressin (used in excessive urination)

Pregnancy, breastfeeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your physician for advice before taking this medicine.

It is not recommended to take this medicine during pregnancy.

It is not recommended to use Loperamid Slavia if you are breast-feeding, because small amounts of Loperamid Slavia are excreted in your milk.

Pregnant or lactating women should therefore be advised to consult their physician for appropriate treatment.

Driving vehicles and use of machineries

If during treatment (or as a result of diarrhea) you feel tired, sleepy or dizzy, you are less alert or you have a feeling of fainting, avoid driving and using machinery.

Loperamid Slavia contains lactose

If your physician has warned you that you have an intolerance to some categories of carbohydrates, please ask him before taking this medicine.

Loperamid Slavia contains methyl para-hydroxybenzoate (E218) and propyl para-hydroxybenzoate (E216), which may induce (even delayed) allergic reactions.

3. How to use Loperamid Slavia

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

Acute diarrhea

Adults and teenagers over the age of 12

The recommended initial dose is 4 mg loperamide hydrochloride (two Loperamid Slavia capsules) administered orally, followed by 2 mg loperamide hydrochloride (one Loperamid Slavia capsule) after each diarrheal stool.

Chronic diarrhea

Adults and teenagers over the age of 12

The recommended initial dose is 4 mg loperamide hydrochloride per day (two Loperamid Slavia capsules) for adults and 2 mg loperamide hydrochloride per day (one Loperamid Slavia capsule) for teenagers. This initial dose should be adjusted until 1-2 solid stools per day are obtained. This is usually done with a maintenance dose of 1-6 capsules (2 mg-12 mg loperamide hydrochloride) per day.

The maximum dose for acute and chronic diarrhea is 8 capsules (16 mg) per day for adults, in teenagers the dose should be related to body weight (3 capsules/20 kg) but should not exceed a maximum of 8 capsules per day.

Elderly patients

No dose adjustment is necessary in the elderly.

Children under the age of 12

For children under the age of 12, age-appropriate pharmaceutical forms and concentrations are recommended.

If the stools become normal or if a stool has not been passed for 12 hours, stop the administration of Loperamid Slavia.

If you have any questions, ask your physician or pharmacist.

If you take more Loperamid Slavia than you should

If you have taken too much Loperamid Slavia, contact a physician immediately or go to the nearest hospital for advice. Symptoms may include: fast heartbeat, irregular heartbeat, changes in the rhythm of the heartbeat (these symptoms can have potentially serious consequences, which can put your life in danger), muscle stiffness, uncoordinated movements, drowsiness, difficulty urinating or difficulty breathing.

Children react more strongly than adults to large amounts of Loperamid Slavia. If a child takes too much Loperamid Slavia or if he/she shows any of the above symptoms, see a physician immediately.

If you forget to take Loperamid Slavia

Do not take a double dose to make up for a forgotten dose.

If you have any questions regarding this medicine, talk to your physician or pharmacist.

4. Possible adverse reactions

Like all medicines, Loperamid Slavia can cause adverse reactions, even though those do not occur in all patients.

Stop using Loperamid Slavia and tell your physician immediately if you notice any of the following. You may need emergency medical treatment.

- allergic reactions that include unexplained wheezing, difficulty breathing, fainting or swelling of the face or neck;
- skin rashes which can be severe and include skin blisters or scaling. These can be signs of a severe allergic reaction;
- loss of consciousness or reduced level of consciousness (fainting or reduced alertness), coordination disorders.

Tell your physician immediately if you notice any of the following adverse reactions:

Uncommon adverse reactions (may affect up to 1 in 100 people):

- itching or rash
- stomach aches or stomach swelling

Rare adverse reactions (may affect up to 1 in 1,000 people):

- difficulties in urination
- severe constipation
- obstruction, dilation of the large intestine
- paralysis (inability to contract) of the muscles of the intestine, which prevents the elimination of its content
- miosis (shrinking of the pupils)

Other adverse reactions that may appear

Common adverse reactions (may affect up to 1 in 10 people):

- nausea
- constipation
- bloating
- headaches

Uncommon adverse reactions (may affect up to 1 in 100 people):

- dizziness, drowsiness
- vomiting, indigestion
- dry mouth

Rare adverse reactions (may affect up to 1 in 1,000 people):

- fatigue
- increase in muscle tone

Reporting of adverse reactions

If you get any adverse reactions, talk to your physician or pharmacist. These include any possible adverse reactions not listed in this leaflet. Also, you can report adverse reactions directly through the national reporting system, details of which are published on National Agency for Medicines and Medical Devices of Romania web-site <http://www.anm.ro/>. By reporting adverse reactions, you can help provide additional information about the safety of this medicine.

5. How to store Loperamid Slavia

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

Store at temperatures lower than 25°C.

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.

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 does Loperamid Slavia contain**

- The active substance is loperamide hydrochloride. Each capsule contains loperamide hydrochloride 2 mg.
- The other components are:
 - *capsule content*: lactose monohydrate, corn starch pregelatinised, anhydrous colloidal silicon dioxide, magnesium stearate;
 - *capsule*: titan dioxide (E 171), Patent Bleu V (E131), Quinoline Yellow (E 104), Allura Red AC (E 129), methyl p-hydroxybenzoate (E 218), propyl p-hydroxybenzoate (E 216), gelatine.

What Loperamid Slavia looks like and contents of the pack

Loperamid Slavia comes in the forms of hard gelatinous capsules, no. 4, with opaque green cap and opaque grey body, containing a white to almost white granulated powder.

Loperamid Slavia 2 mg is available in boxes with one PVC/AL blister of 10 capsules.

Marketing authorisation holder and manufacturer

S.C. Slavia Pharm S.R.L.

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Bucharest, Romania

This leaflet was revised in August 2019.