

PACKAGE LEAFLET: Information for the patient

LOPERAMID

Tablets – 2 mg

(Loperamide hydrochloride)

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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Loperamid is and what it is used for
2. Before you take Loperamid
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1. WHAT LOPERAMID IS AND WHAT IT IS USED FOR

Loperamid is a potent synthetic antidiarrheal. It acts directly in the bowel walls, where it binds with the opiates receptors, which slow the intestinal motility. Loperamid in this way inhibits peristalsis activity, which leads to the reduction of the fluid and electrolytes loss from the gut. In this way the daily stool volume is reduced, while the density and viscosity of the mass increases. Loperamid is used in the symptomatic treatment of acute diarrhea of different etiologies, including the acute worsening of acute diarrhea in adults and children above 12 years old (in the age between 6-12 years, it should be used only under medical prescription).

In the treatment of chronic diarrhea, it is used only in adults.

In patients with ileostomy, it may be used to reduce the number and volume of defecation and to increase the consistency of stools.

2. BEFORE YOU TAKE LOPERAMID

Do not take Loperamid if:

- you are hypersensitive (allergic) to loperamide hydrochloride or to any of the excipients of the tablet;
- inhibition of peristalsis must be avoided, because in these cases there is a risk for the development of ileus, megacolon and toxic megacolon;
- you have abdominal flatulence, ileus, constipation; the treatment must be interrupted immediately;
- you suffer from pseudomembranous colitis caused by the use of broad-spectrum antibiotics;
- you suffer from acute ulcerative colitis;
- you suffer from bacterial enterocolitis caused by *Shigella*, *Salmonella*, *Campylobacter*.

Loperamid should not be used alone in acute dysentery, which is characterized from bloody stool and high fever.

Loperamid is contraindicated in hepatic insufficiency because of the possibility of relative overdose.

Loperamid should not be used in children younger than 6 years old, while in the age between 6-12 years old it is not recommended and can be used only under medical prescription.

Take special care with Loperamid

Ask your doctor before you take Loperamid.

Loperamid has a symptomatic effect in acute and chronic diarrhea with non-infectious origin.

During diarrhea the body loses liquids, that is why you should take fluids and electrolytes and implement a suitable diet. This is especially important for children.

If the diarrhea is not controlled within 48 hours, then other causes of this pathology must be identified.

Long-term use of Loperamide is best to be avoided.

Care must be done in the elderly and in patients with significant impairment of the liver function, in which signs of toxic effects on the central nervous system can become visible.

In the slightest suspicion for toxic megacolon, treatment with Loperamid must be interrupted immediately.

There is no data about harmful effects of the drug during pregnancy. However, in this period it should be used only in emergencies and only when the potential benefit for the mother justifies the potential risk to the fetus.

Although the amount of drug that is excreted in breast milk is very low, it is recommended that breast - feeding should be interrupted during the treatment.

In particular patients Loperamid may cause dizziness and fatigue. In such cases, don't drive and don't use machinery until the adverse effects disappear completely.

It is not recommended the use of tablets under 12 years old.

Do not take this product for anything other than its intended use and never take more than the recommended amount. (section 3) Serious heart problems (symptoms of which include fast or irregular heartbeat) have been reported in patients who have taken too much loperamide.

Taking other medicines

Simultaneous treatment with other medicines may affect or be affected by Loperamide.

Please tell your doctor or pharmacist if you are taking / using, have recently taken / used or might take / use any other medicines, including medicines obtained without a prescription.

Don't forget to inform your doctor for the treatment with Loperamid if you receive any other medicine during treatment.

It is especially important that your doctor is aware of the fact that you are treated with:

- opioid analgesics, because the combined treatment of loperamide with opioid analgesics may cause severe constipation;
- drugs that inhibit or accelerate gastrointestinal peristalsis;
- desmopressin: loperamide increases the plasmatic concentration of oral desmopressin;
- itraconazole: it increases the plasmatic concentration of loperamide;
- ritonavir: it increases the bioavailability of loperamide;
- gemfibrozil: it increases the plasmatic concentration of loperamide;
- co-trimoxazole: it increases the bioavailability and inhibits the hepatic metabolism of loperamide;
- quinidine: it increases the entrance of loperamide in the central nervous system.

Loperamide may be used with other drugs: chemotherapeutics, corticosteroids, anthelmintics.

Taking Loperamid with food and drinks

It can be taken with half a glass of water.

Pregnancy

Seek the advice of a pharmacist or doctor before taking this medicine.

There are no data on the harmful effects of the drug during pregnancy. However, in this period it should be used only in emergencies and only when the potential benefit for the mother justifies the potential risk to the fetus.

Breastfeeding

Although the part of drug that is excreted in breast milk is very low, it is recommended that breastfeeding should be interrupted during treatment.

Driving and using machines

In particular patients, Loperamid can cause dizziness and fatigue. In these cases, you should not drive and use machinery until the adverse effects disappear completely.

Important information about some of the excipients of Loperamid

This medicine contains 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 LOPERAMID

Always take Loperamid according to medical or pharmacist advice. If you are not sure, contact your doctor or pharmacist. If you feel that the effects of Loperamid are too strong or too weak, contact your doctor or pharmacist. The tablets should be taken with at least half glass of water. The treatment of diarrhoea usually starts with the replacement of the lost fluids (rehydration by mouth).

Based on the opinion of the doctor or pharmacist, you may start the concomitant treatment with loperamide. If after 48 hours, a suitable therapeutic effect is not achieved, the treatment with

loperamide should be interrupted.

Acute diarrhoea:

Adults and children of 12 years of age and over

4 mg (2 tablets) followed by 2 mg (1 tablet) after every loose stool.

The usual dose is 3-4 tablets a day. The dose of 8 tablets (16 mg) per day should not be exceeded.

Children under 12 years old

Loperamid must not be used in children under 6 years old, while in the age between 6 - 12 years old it is not recommended and can be used only under medical prescription.

Chronic diarrhoea

It is used in adults only and the dose is defined from the doctor.

Your doctor will advice you according to the circumstances.

If you take more Loperamid than you should

If you have taken too many Loperamid tablets, immediately contact a doctor or hospital for advice.

Symptoms may include: increased heart rate, irregular heartbeat, changes to your heartbeat (these symptoms can have potentially serious, life-threatening consequences), muscle stiffness, uncoordinated movements, drowsiness, difficulty urinating, or weak breathing.

Children react more strongly to large amounts of Loperamid than adults. If a child takes too much or shows any of the above symptoms, call a doctor immediately.

If you forget to take Loperamid

If you forget a dose (or more doses), take the following dose when it is time to take it usually.

Do not take a double dose (or higher) to make up the forgotten dose (doses).

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

4. POSSIBLE SIDE EFFECTS

Like all other medicines, Loperamid can cause side effects, although not everyone manifests them. Sometimes they are serious, sometimes not. Do not be alarmed from this list of possible side effects. You may not experience any of them.

At the recommended doses and when contraindications are taken into account, no significant side effects have been reported, even after long-term use. The side effects reported from the use of loperamide are difficult to distinguish from symptoms accompanying the diarrhoeal syndrome.

Side effects that may appear are:

Common or very common: dizziness, flatulence (presence of gas in the abdomen), headache, nausea, constipation.

Uncommon: abdominal pain, drowsiness, dry mouth, dyspepsia, rash, vomiting.

Rare: fatigue, hypertonia, paralytic ileus, Stevens-Johnson syndrome, toxic epidermal necrolysis, urinary retention.

Not known: Upper abdominal pain, abdominal pain that radiates to back, tenderness when touching the abdomen, fever, rapid pulse, nausea, vomiting, which may be symptoms of inflammation of the pancreas (acute pancreatitis).

In case of overdose, central nervous system depression may appear. Children and those with hepatic impairment are more sensitive.

If any of the side effects gets worse, or if you notice any side effect not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE LOPERAMID

Keep out of the reach and sight of children!

Do not use Loperamid after the expiry date which is stated on the packaging.

Do not store above 25°C!

Keep in the original packaging to protect it from light and humidity!

6. FURTHER INFORMATION

What Loperamid 2 mg tablets contain

The active substance is loperamide hydrochloride.

Each tablet contains 2 mg loperamide hydrochloride.

The excipients are lactose, magnesium stearate, microcrystalline cellulose, and talc.

Content of the pack

Box with 20 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA Sh.a.,

St. "Skënder Vila",

Tirana, Albania.

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