

 **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 signs of illness are the same as yours.
- If any of the side effects gets worse or if you notice side effects not listed in this leaflet, talk to your doctor or pharmacist.

**In this leaflet:**

1. What Loperamid is and what it is used for
2. Before you take Loperamid
3. How to take Loperamid
4. Possible side effects
5. How to store Loperamid
6. Other informations

**1. WHAT LOPERAMID IS AND WHAT IT IS USED FOR**  
Loperamide is a synthetic potent antidiarrhoeic. It acts directly in the intestinal walls, where it binds with opiate receptors, which slow the gut motility. Loperamid inhibits in such way peristaltics, which reduces fluids and electrolytes loss from the intestine. Thus, the daily volume of stools is reduced, while the consistency and density of the mass increases.  
About 40% of the drug used orally is absorbed intestinally. Serum maximal concentrations are achieved 5 hours after taking the tablets. The apparent elimination half – life is 10.8 hours (varies from 9.1 to 14.4 hours). From a dose of 4 mg, about 25% is excreted unchanged with the feces and 1.3% is excreted with the urine as free drug and conjugated with glucuronic acid within 3 days. Loperamid is used for the symptomatic treatment of acute diarrhoea of different ethiology, including also acute worsening of acute diarrhoea for a period of till 5 days in adults and children over 2 years and chronic diarrhoea in adults. Loperamid, in patients with ileostomia, may be used to decrease the number and volume of defecations and to increase the consistency of feces.

**2. BEFORE YOU TAKE LOPERAMID**  
Do not take Loperamid if you are hypersensitive (allergic) to loperamide hydrochloride or to any of the other ingredients of Loperamid.  
Loperamid should not be used when peristaltic inhibition should be avoided, especially when ileus and constipation are present or when abdominal bloating appears, especially in very dehydrated children or in patients with acute ulcerative colitis and with pseudomembranous colitis, when antibiotics with a broad-spectrum activity are also used.  
Loperamid should not be used alone in acute dysentery, which is characterized with bloody stools and high temperature.  
Loperamid is contraindicated in liver failure because of the possibility of relative overdose; for the same reason Loperamid should not be used in children under 2 years.

**Take special care with Loperamid**  
Ask your doctor before you take Loperamid.  
Loperamid has a symptomatic effect in acute and chronic diarrhoea with non-infective origin. Patients should take fluids and electrolytes, and follow a suitable diet. If diarrhea is not controlled within 48 hours, other causes of this pathology should be identified.  
Long-term use of Loperamid should better be avoided.  
Special care should be taken in young children because of considerable fluctuations in response, especially when the children are dehydrated.  
Also, care is necessary in older people and patients with severe liver function impairment, in whom signs of toxic effects in central nervous system may become apparent.  
If there is a minimal doubt for toxic megacolon, treatment with Loperamid must be stopped immediately.  
There are no data for harmful effects of the medicine during pregnancy. However, during this period it should be used only in urgent cases and only when the potential benefit for the mother justifies the potential risk for the fetus.  
Although the quantity of the medicine which is excreted in breast

milk is very low, it is recommended that lactation be interrupted during treatment.  
In some patients, Loperamid, although in rare cases, can cause dizziness and fatigue. In such cases, patients should be advised by the doctor and pharmacist not to drive and not to use machinery until the undesirable effects disappear completely.  
Loperamid does not impair psychomotor abilities and it does not cause sedation and drowsiness.

**Taking other medicines**  
Concomitant treatment with other medicines may influence or be influenced by Loperamid.  
Contact your doctor or pharmacist if you are taking or have recently taken other medicines, including those taken without a prescription. Don't forget to inform your doctor for the treatment with Loperamid if you are given another medicine during therapy.  
It is particularly important that your doctor be informed that you are being treated with opiate analgesics because the combined use of Loperamid with opiate analgesics may cause severe constipation. Loperamid may also be used with other medicines (e.g. chemotherapeutics, corticosteroids, antihelmintics).

**Taking Loperamid with food and drinks**  
It can be taken with half glass of water.

**Pregnancy**  
**Ask your doctor or pharmacist for advice before you take this medicine.**  
There are no data for harmful effects of the medicine during pregnancy. However, during this period it should be used only in urgent cases and only when the potential benefit for the mother justifies the potential risk for the fetus.

**Breastfeeding**  
Although the quantity of the medicine which is excreted in breast milk is very low, it is recommended that breastfeeding be interrupted during treatment.

**Driving and using machines**  
In some patients, Loperamid, although in rare cases, can cause dizziness and fatigue. In such cases, patients should be advised by the doctor and pharmacist not to drive and not to use machinery until the undesirable effects disappear completely.

**3.HOW TO TAKE LOPERAMID**  
Always take Loperamid as your doctor has told you. Check with your doctor or pharmacist if you are not sure. If you notice that the effects of Loperamid are too strong or too weak, talk to your doctor or pharmacist. The tablets should be taken with at least half glass of water.

The dosage of Loperamid is as follows:  
Treatment of diarrhoea usually starts with the replacement of lost fluids (oral rehydration). Based on the doctor's considerations, concomitant treatment with loperamide may be initiated. If after 48 hours a suitable therapeutic effect is not achieved, treatment with Loperamid should be discontinued.

A practical table is given below for the dosage of Loperamid.

Age	Daily dose 1 tablet = 2 mg	
	Initial treatment	Uterior treatment
Adults and children over 12 years	2 tablets, afterwards 1 tablet after each defecation	1 tablet after each defecation; maximum 8 tablets
Children 8 – 12 years	1 tablet, afterwards 1 tablet after each defecation	Maximum 6 tablets
Children 5 – 8 years		Maximum 4 tablets
Children 2 – 5 years		Maximum 1.5 tablets

It may be necessary to increase or to reduce the dose. Your doctor will tell you what to do.

**If you take more Loperamid than you should**  
If you take more Loperamid than you should, or if the children take it accidentally, contact your doctor, the hospital or call the emergency to get an opinion of the risk and advice on the actions to be taken.

**If you forget to take Loperamid**  
If you forget a dose (or more), take the next dose when it is time for its usual take.  
Do not take a double dose (or higher) to make up for a forgotten dose (s).  
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4.POSSIBLE SIDE EFFECTS**  
Like all medicines, Loperamid can cause side effects, although not everybody gets them. Sometimes they are serious, sometimes not. Do not be alarmed by this list of possible side effects. You may get none of them.  
In the recommended doses and when contraindications are taken in consideration, no important side effects have been observed, even after long-term treatment. It is difficult to distinguish side effects reported from Loperamid use from the symptoms which accompany diarrhoeic syndrome.  
The possible side effects are:  
• hypersensitivity reactions (including exanthemas),  
• bloating and discomfort,  
• nausea,  
• vomiting,  
• abdominal pain,  
• constipation,  
• somnolence,  
• dizziness,  
• dry mouth.  
If any of the side effects gets worse or if you notice side effects not listed in this leaflet, talk to your doctor or pharmacist.


**5. HOW TO STORE LOPERAMID**  
Keep this medicine out of the sight and reach of children.  
Do not use Loperamid after the expiry date, which is stated on the package.  
Store below 25°C.

Store in the original package to protect it from light and humidity.


**6. OTHER INFORMATIONS**  
**What Loperamid – Tablets 2 mg contain**  
The active substance is Loperamide hydrochloride.  
Each tablet contains 2 mg loperamide hydrochloride.  
The other excipients are: lactose, magnesium stearate, microcrystalline cellulose, talc.

**Content of the pack**  
Box with 20 tablets.


### Explanatory of the illustration icons on the packaging:




Ask your doctor or pharmacist.




Be careful during pregnancy. Ask your doctor or pharmacist.




Should not be used in children.



Contents.



Warning.



Tablet shape.

### Marketing authorization holder (MAH) and manufacturer:



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