

Package leaflet: Information for the user

Loperamide Medical Valley 2 mg tablets loperamide hydrochloride

[Rx]

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told 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.

[OTC in IS]

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Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 days.

What is in this leaflet:

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

1. What [Invented name] is and what it is used for

[Invented name] normalises bowel movements, prevents fluid loss and increases the ability to hold the stools.

[Invented name] is used in temporary (acute) diarrhoea. It may also be prescribed by doctors for other uses such as prolonged (chronic) diarrhoea and in ostomy after certain gastrointestinal operations or in the inability to hold the stools (faecal incontinence).

You must talk to a doctor if you do not feel better or if you feel worse after 2 days.

2. What you need to know before you take [Invented name]

Do not use [Invented name]

- if you are allergic to loperamide or any of the other ingredients of this medicine (listed in section 6),

- when there is blood in the stool or in high fever (intestinal infection caused by bacteria such as Salmonella, Shigella and Campylobacter),
- in inflammation of the colon (e.g., ulcerative colitis or pseudomembranous colitis caused by antibiotics),
- if the passage of food through the intestine is already slow, for example if you are constipated or disturbed by abdominal distension.

Do not give [Invented name] to children under 12 years of age.

Warnings and precautions

Treatment with [Invented name] relieves symptoms but does not cure the cause. Prior to long-term treatment, the underlying disease must therefore be investigated and treatment against it should be initiated first.

- If temporary diarrhoea has not ceased after two days of treatment, discontinue treatment, and consult a doctor.
- In case of signs of constipation or other signs of impaired bowel passage, discontinue treatment and consult a doctor.
- If you have impaired liver function, you should consult your doctor before starting treatment with [Invented name].
- In diarrhoea conditions, you lose a lot of fluid. It is therefore important that you replace the fluid loss by drinking a lot.
- If you have AIDS, stop treatment with [Invented name] at the first sign of abdominal distension.

Do not take this medicine for anything other than its intended use (see section 1) and never take more than the recommended dose (see section 3). Serious heart problems (with symptoms such as fast or irregular heartbeats) have been reported in patients taking too much loperamide, the active ingredient in [Invented name].

Children and adolescents

Do not give [Invented name] to children under 12 years of age.

Other medicines and [Invented name]

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

Some medicines may affect or be affected by the treatment with [Invented name] if taken at the same time. Examples of such medicines are:

- cholestyramine and gemfibrozil (lowering blood fat),
- quinidine (for heart rhythm disorders and malaria),
- ritonavir (against HIV/AIDS),
- ciclosporin (inhibits the immune system),
- verapamil (lowering blood pressure),
- erythromycin and clarithromycin (antibiotics),
- itraconazole and ketoconazole (antifungal agents),
- oral desmopressin (drugs used to control thirst and urine production in patients with diabetes insipidus and bedwetting in children and nocturnal urinary incontinence in adults)

Pregnancy and breast-feeding

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.

Pregnancy

There is limited experience in the use of this medicine during pregnancy. If you are pregnant or think you may be pregnant, ask your doctor for advice before taking [Invented name].

Breast-feeding

[Invented name] is not recommended if you are breast-feeding as small amounts of the drug may pass into breast milk.

Driving and using machines

Fatigue, dizziness and drowsiness may occur during treatment with [Invented name].

[Invented name] contains lactose

[Invented name] 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 [Invented name]

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

The recommended dose is:

In case of temporary diarrhoea:

Common dose for adults and adolescents from 12 years: Start with 2 tablets. If the diarrhoea has not stopped within 2-3 hours, take 1 tablet at a time after each loose stool. Take no more than 8 tablets per day. Take [Invented name] for a maximum of 2 days in a row. Doctors may prescribe different dosages.

In chronic diarrhoea: The dose is determined by the doctor who will adjust it individually for you.

Common dose for adults and adolescents from 12 years: 1-8 tablets/day. Take no more than 8 tablets per day.

The tablets should be swallowed whole with half a glass of water.

Diarrhoea-counteracting effect is achieved within one hour after taking 2 tablets (4 mg).

If you take more [Invented name] than you should

If you take more [Invented name] than you should, or if children have been taking medicine by accident, contact your doctor or hospital immediately for advice. Symptoms may include increased heart rate, irregular heartbeat, changes in heartbeat (these symptoms can potentially have serious, life-threatening consequences), muscle rigidity, uncoordinated movements, drowsiness, difficulty urinating, or poor breathing.

Children react more strongly than adults to large amounts of [Invented name]. Contact a doctor immediately if a child has too much of the drug or has any of the above symptoms

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

If you forget to take [Invented name]

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

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.

Stop taking [Invented name] and contact your doctor immediately if you experience any of the following:

rare symptoms:

- swelling of the face, tongue or throat, difficulty swallowing or hives and difficulty breathing. These are signs of angioedema.
- extreme fatigue, coordination problems and loss of consciousness or reduced consciousness.
- severe abdominal pain and/or swollen stomach which may be a sign of blocked or enlarged bowel.
- *Lyell's syndrome (toxic epidermal necrolysis)*: Severe widespread skin damage (exfoliation of the epidermis and superficial mucosa).
- *Stevens-Johnson Syndrome*: An extremely severe allergic reaction with a rash usually in the form of blisters or ulcers in the mouth and eyes and other mucous membranes such as genitalia.

not known (frequency cannot be estimated from the available data):

- 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).

Other side effects that may occur:

Common (may affect up to 1 in 10 people): constipation, nausea, flatulence/gas formation, headache and dizziness.

Uncommon (may affect up to 1 in 100 people): drowsiness, pain or stomach discomfort, dry mouth, vomiting, indigestion and rash.

Rare (may affect up to 1 in 1,000 people): hypersensitivity reactions such as anaphylactic shock, muscle rigidity, small pupils, pruritus, hives and difficulty in urinating.

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** listed in [Appendix V](#).^{*} By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Invented name]

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

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

This medicinal product does not require any special storage conditions.

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**Contents**

- The active substance is: loperamide hydrochloride 2 mg.
- The other ingredients are: Lactose, Maize starch, Polysorbate 80 (E433), Talc (E 553 b), Colloidal anhydrous silica and Magnesium stearate (E 572).

What [Invented name] looks like and contents of the pack

Tablets 2 mg: white to off white, 6.5 mm, round, biconvex, uncoated tablets debossed with “C” on one side and “11” on other side.

Available in blister packs of 20 and 60 tablets.

Available in plastic container of 45, 105 and 270 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

<[To be completed nationally]>

{Name and address}

Manufacturer

PharmaS d.o.o.

Industrijska cesta 5

44317 Potok, Popovača,

Croatia

or

Laboratorios Liconsa, S.A

Avda. Miralcampo 7

Polígono Industrial Miralcampo

19200 – Azuqueca de Henares

Guadalajara - Spain

This medicinal product is authorised in the Member States of the EEA under the following names:

Iceland: Loperamide Medical Valley 2 mg töflur

Sweden: Loperamide Medical Valley 2 mg tablett

This leaflet was last revised in 2025-03-13.