

Package leaflet: Information for the user

Imolopera 2 mg tablets

loperamide hydrochloride

Only relevant for RX:

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Only relevant for OTC:

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, pharmacist or nurse have 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, pharmacist or nurse. 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] normalizes bowel movements, neutralizes fluid loss and increases the ability to hold stool.

Only relevant for RX:

[Invented name] is used by adults and adolescents over 12 years of age for:

- temporary (acute) diarrhoea
- long-term (chronic) diarrhoea
- "bag on the stomach" (ostomy) after certain gastrointestinal operations
- inability to hold stools (faecal incontinence).

Only relevant for OTC:

[Invented name] is used for short term (acute) diarrhoea in adults and adolescents over 12 years of age.

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 take [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 if you have a high fever (intestinal infection caused by bacteria e.g. 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.

[Invented name] must not be given to children under 12 years of age.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking [Invented name].

- if short term diarrhoea has not ceased after two days of treatment, discontinue the treatment and contact a doctor.
- in case of signs of constipation or other signs of impaired bowel passage, discontinue the treatment and contact a doctor.
- if you have impaired liver function, you should contact a 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 the treatment with [Invented name] at the first sign of swollen stomach.

Only relevant for RX:

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.

Only relevant for OTC:

Treatment with [Invented name] relieves symptoms but does not cure the cause.

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 (symptoms such as fast or irregular heartbeat) have been reported in patients who have taken too much loperamide hydrochloride, the active ingredient in [Invented name].

Children

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 medicine are:

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

[Invented name] with food and drink

[Invented name] can be taken with food and liquid.

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 loperamide hydrochloride during pregnancy.

Breast-feeding

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

Driving and using machines

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

If affected do not drive or operate machinery

[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]

Only relevant for RX:

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

Only relevant for OTC:

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

The recommended dose is:

Only relevant for RX:

In case of temporary diarrhoea:

Adults and adolescents from 12 years of age: 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 of age: 1-8 tablets per day. Take no more than 8 tablets per day.

Only relevant for OTC:

Adults and adolescents from 12 years of age: 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 a different dosage.

Use in children:

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

The tablets should be swallowed with liquid.

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 have taken more [Invented name] than you should, immediately contact a doctor or hospital for advice. Symptoms may include: increased heart rate, irregular heartbeat, changes to your heartbeat (these

symptoms can have serious, life-threatening consequences), muscle stiffness, uncoordinated movements, drowsiness, difficulty urinating or weak breathing.

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

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, pharmacist or nurse.

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 side effects:

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

- 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 signs of blocked or enlarged bowel.
- Lyell's syndrome (toxic epidermal necrolysis): Severe widespread skin damage (peeling of the skin 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.
- hypersensitivity reactions such as anaphylactic shock, muscle rigidity, small pupils, pruritus, hives and difficulty in urinating.

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

- upper abdominal pain, abdominal pain that radiates to the back, tenderness when touching the abdomen, fever, rapid pulse, nausea, vomiting, which may be symptoms of inflammation of the pancreas (acute pancreatitis).

The following side effects are reported:

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

- constipation
- nausea
- flatulence/gas
- headache and dizziness.

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

- drowsiness
- abdominal pain or discomfort
- dry mouth
- vomiting
- indigestion
- rash.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 this medicine after the expiry date which is stated on the carton. 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 [Invented name] contains

- The active substance is loperamide hydrochloride 2 mg
- The other ingredients are: anhydrous lactose 101 mg; maize starch; polysorbate 80; talc; colloidal, anhydrous silica; magnesium stearate.

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

Tablets are white and round with a diameter of 6.5 mm, one side marked C and the other side marked 11.

Blister pack sizes: 16, 20, 40, 100 and 104 tablets.

Plastic container: 250 tablets (only for dose dispensing).

Plastic container: 250 tablets

Not all pack sizes may be marketed.

Only relevant for OTC:

Each blister pack contains: 16 tablets.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This leaflet was last revised in

2023-03-14

Detailed information on this medicine is available on the web site of {MA/Agency}