

Package leaflet: Information for the user

[Nationally completed name]
loperamide hydrochloride

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

1. What **[Nationally completed name]** is and what it is used for

This medicine contains loperamide hydrochloride which helps to stop diarrhoea by making the stools more solid and less frequent. This medicine is used for the treatment of sudden short-lived (acute) attacks of diarrhoea in adults and adolescents over 12 years of age. **This medicine must not be used for more than 2 days without medical advice and surveillance.**

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 **[Nationally completed name]**

Do not take **[Nationally completed name], if:**

- patients with a known hypersensitivity to loperamide hydrochloride or to any of the excipients (listed in section 6);
- children aged less than 2 years of age
- patients with acute dysentery, which is characterised by blood in stools and elevated body temperature.
- patients with acute ulcerative colitis
- patients with bacterial enterocolitis caused by invasive organisms including Salmonella, Shigella and Campylobacter
- patients with pseudomembranous colitis associated with the use of broad spectrum antibiotics
- in all cases where normal bowel movements should not be suppressed. Administration should be stopped immediately in case of constipation or abdominal swelling.

If any of these applies to you, talk to a doctor or pharmacist before taking loperamide hydrochloride.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking this medicine, if:

- you have AIDS and your stomach becomes swollen, stop taking the oral lyophilisates immediately and see your doctor immediately;
- you suffer from liver disease;

- you have diarrhoea that lasts for more than 48 hours stop taking the medicine and consult your doctor.
- you have severe diarrhoea, you will lose a lot of fluid (dehydration). With this fluid, other important substances are also lost. Symptoms of dehydration may include dry mouth and/or dizziness. The vomiting may lead to dehydration. Danger of dehydration exists especially in young children and the elderly. They should therefore be the first measure for diarrhoea: supplement and maintain the fluid in the body. That means: drink a lot, and supplement sugar and salt. At the pharmacy or drug store you can get a special salt-sugar mixture (ORS), which has to be dissolved in water. Ask your doctor or pharmacist for advice.

Other medicines and [Nationally completed name]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular if you are taking any of the following medicines;

- ritonavir (used to treat HIV)
- quinidine (used to treat abnormal heart rhythms or malaria)
- oral desmopressin (used to treat excessive urination)
- itraconazole or ketoconazole (used to treat fungal infections)
- gemfibrozil (used to treat high cholesterol).

If you are not sure about any of the medicines you are taking, show the bottle or pack to your pharmacist. If any of these applies to you (now or in the past), talk to a doctor or pharmacist.

Pregnancy, breast-feeding and fertility

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: The use of [nationally completed name] should be avoided during pregnancy, especially during the first trimester of pregnancy.

Breast-feeding: Small amounts may get into your milk. Talk to your doctor about a suitable treatment.

Driving and using machines

During diarrhoea you can feel dizzy, tired or sleepy. If affected you should not drive or operate machinery or take part in activities where these may put you or others at risk.

Excipients

This medicine contains less than 1 mmol (23 mg) sodium per oral lyophilisate, that is to say essentially 'sodium-free'.

This medicine contains 1.0 mg aspartame in each oral lyophilisate. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly

3. How to take [Nationally completed name]

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

Check the table below to see how much medicine to take.

- Peel back the lid and tip the oral lyophilisate out. Do not push the oral lyophilisates through the lid.
- Place the correct number of oral lyophilisates on the tongue. The oral lyophilisates dissolve quickly in your mouth, so you don't need water to swallow them. Do not chew. For oral use only.
- Do not use more than the dose shown in the tables.
- The oral lyophilisates are not for long-term treatment.

Short-term diarrhoea

Age	Initial dose	Repeat dose	Max. daily dose
Adolescents aged 12 years and over	1 oral lyophilisate	1 oral lyophilisate after each loose stool, not earlier than 1 hour after the initial dose.	4 oral lyophilisates
Adults	2 oral lyophilisates	1 oral lyophilisate after each loose stool, not earlier than 1 hour after the initial dose.	6 oral lyophilisates

Do not exceed the max. daily dose.

Do not take for attacks lasting longer than 2 days.

Replace lost fluid by drinking more liquid than usual.

Elderly

No dose adjustment is required for the elderly.

Kidney problems

No dose adjustment is required for patients with impaired kidney function.

Liver problems

If you suffer from liver impairment you should ask your doctor or pharmacist before you take this medicine.

How long to take [Nationally completed name] for short-term diarrhoea

You can use this medicine for up to 48 hours.

If the attack of diarrhoea lasts longer than 48 hours, or if you suffer from repeated diarrhoeal attacks or if your symptoms change, stop taking loperamide hydrochloride and talk to your doctor.

If you take more [Nationally completed name] than you should

If you have taken too many loperamide hydrochloride 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 loperamide hydrochloride than adults. If a child takes too much or shows any of the above symptoms, call a doctor immediately.

If you forget to take [Nationally completed name]

You should only take this medicine as you need it, following the dosage instructions above carefully.

If you forget to take a dose, take a dose after the next loose stool (bowel movement). Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them, most are usually mild.

Get medical help at once

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

- Feeling sick, constipation or wind.
- Headache.

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

- Itchiness or hives.
- Stomach pain or swollen stomach.
- Dizziness or drowsiness.
- Vomiting, indigestion.
- Dry mouth.

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

- Allergic reactions including unexplained wheezing, shortness of breath, passing out or swelling of face and throat.
- Skin rashes, which may be severe and include blistering or peeling skin.
- Loss of consciousness or reduced level of consciousness (passing out, feeling faint or less alert), uncoordinated movements.
- Difficulties passing water.
- Severe constipation.
- Burning or prickling sensation of the tongue.
- Miosis (narrowing of the pupils of the eye).
- Tiredness.

If you get any of these, stop using the medicine and get medical help at once. **Talk to a doctor as soon as possible.**

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 [Nationally completed name]

Keep the product out of the sight and reach of children.

This medicinal product does not require any special storage conditions Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not throw away 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 [Nationally completed name] contains

The active substance(s) is loperamide hydrochloride.

Each oral lyophilisate contains 2 mg loperamide hydrochloride.

Other Ingredients are: pullulan (E1204), mannitol (E421), sodium hydrogen carbonate (E500), aspartame (E951), polysorbate 80 (E433), peppermint flavour (corn maltodextrin, flavouring Ingredients and modified waxy maize starch, 1450).

What [Nationally completed name] looks like and contents of the pack

Oral lyophilisate.

Blister packaging in packs of 6 or 12 oral lyophilisates and 10 oral lyophilisates

The blister comprising PVC/polyamide/aluminium/PVC blister with peel-off lidding of paper/PET/aluminium foil.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

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