



**Package leaflet:
Information for the user**

**Loperamide 2 mg
Hard Capsules**

loperamide
hydrochloride

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 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.

What is in this leaflet

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

1. What Loperamide is and what it is used for

This medicine contains Loperamide 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 children over 12 years of age.

Please note that this medicine only relieves the symptoms of diarrhoea and it is important to drink sufficient fluid to replace the water lost in the loose stools.

2. What you need to know before you take Loperamide

Do not take Loperamide:

- You are allergic to loperamide or to any of the other ingredients in this medicine (listed in section 6).
- You suffer from colitis (inflammation of the colon) or any other inflammatory bowel disease, such as ulcerative colitis.
- You have severe diarrhoea after taking antibiotics.
- You have a swollen stomach or tummy, and/or constipation.
- You are suffering from acute dysentery the symptoms of which may include blood in your stools and a high temperature.
- if it is for a child aged below 12

If any of these apply to you, get advice from a doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Loperamide

- If you have AIDS and your stomach becomes swollen. Stop taking the capsules immediately and contact your doctor.
- If you suffer from liver problems.
- If you have severe diarrhoea as your body loses more fluid, sugars and salts than normal.
- If your diarrhoea lasts for more than 48 hours stop taking the capsules and consult your doctor.
- If you develop a bowel obstruction stop taking the capsules and consult your doctor.

- If you have an intolerance to some sugars, unless your doctor tells you to (this medicine contains lactose)

Do not take this product for anything other than its intended use (see section 1) and never take more than the recommended amount (see section 3). Serious heart problems (symptoms of which include fast or irregular heartbeat) have been reported in patients who have taken too much loperamide, the active ingredient in Loperamide.

Children

Not recommended for children under 12 years of age.

Other medicines and Loperamide

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other 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 levels of lipids in the blood).
- anti-cholinergic drugs

Consult a doctor before taking Loperamide if you use any of the above mentioned medicines.

Loperamide with food and drink

You can take Loperamide with food and drink.

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.

Do not take this medicine if you are breastfeeding as small amounts may get into your milk. Talk to your doctor about a suitable treatment.

Driving and using machines

This medicine may make you feel dizzy, tired or sleepy. You may also lose consciousness, feel faint or less alert. If affected do not drive or operate machinery.

Loperamide 2 mg Hard Capsules 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 Loperamide

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

Adults, the elderly and children over 12 years
<p>How to take: The capsules should be swallowed whole with a drink of water.</p> <p>Dose and how often to take: After the first loose stool (bowel motion) take 2 capsules with water.</p>

After each further loose stool, take 1 capsule.

<p>Rehydration sachets are available separately.</p> <ul style="list-style-type: none"> • Do not give to children under 12 years of age. • Do not take more than 6 capsules in any 24 hours. • If symptoms persist for more than 48 hours, stop taking the capsules and consult your doctor. • Replace lost fluid by drinking more liquid than usual. • DO NOT EXCEED THE STATED DOSE.
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If you take more Loperamide than you should

Contact your doctor or nearest Accident and Emergency department (Casualty) taking this leaflet with you.

If you have taken too many Loperamide, 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, contraction of the pupil, difficulty urinating, or weak breathing, fainting.

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

If you forget to take Loperamide

You should only take this medicine as required following the dosage instructions 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.

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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

If you experience any of the following stop using the medicine and seek immediate medical help: Rare: may affect up to 1 in 1,000 people

- Allergic reactions including unexplained wheezing, shortness of breath, swelling of the face and throat
- Loss of consciousness or reduced level of consciousness (feeling faint or less alert)
- Skin rashes which may be severe and include blistering and peeling of the skin.

Other side effects

If you experience any of the following stop taking the medicine and talk to your doctor:

Common: may affect up to 1 in 10 people

- Headache, dizziness
- Nausea (feeling sick), constipation, flatulence (wind).

Uncommon: may affect up to 1 in 100 people

- Tiredness, drowsiness
- Stomach pains, vomiting, indigestion and heartburn, dry mouth.
- Rash

Rare: may affect up to 1 in 1000 people

- Itchiness or hives
- Constriction of the pupil
- Difficulty passing water (urine)
- A swollen stomach, a burning sensation in the mouth, lips or tongue
- Fatigue.

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 Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Loperamide

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 after EXP. The expiry date refers to the last day of that month.

Store below 30°C.

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 Loperamide contains

- The active substances is loperamide hydrochloride.

Each hard capsule contains 2 mg of loperamide hydrochloride.

- The other ingredients are:

Capsules content: Lactose monohydrate, maize starch, talc, magnesium stearate.

Capsules shell: Titanium dioxide (E171), gelatin.

Printing Ink: Shellac, black iron oxide (E172).

What Loperamide looks like and contents of the pack

Hard Capsule.

White opaque cap/White opaque body, size '4' hard gelatin capsule shells, imprinted with '2' on cap and 'L' on body with black ink filled with white to off-white powder.

Loperamide hard capsules are available in clear PVC/Aluminium blisters pack.

Pack sizes:

Blister packs: 6, 8, 10, 12, 15, 18, 20, 30 & 50 hard capsules.

Not all pack sizes may be marketed.

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