

PACKAGE LEAFLET: INFORMATION FOR THE USER

Loperamide 2 mg Tablets

(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. 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.

In this leaflet:

1. What **Loperamide Tablets** are and what they are used for
2. What you need to know before you take **Loperamide Tablets**
3. How to take **Loperamide Tablets**
4. Possible side effects
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6. Contents of the pack and other information

1. WHAT LOPERAMIDE TABLETS ARE AND WHAT THEY ARE USED FOR

The name of your medicine is Loperamide 2 mg Tablets. In the rest of this leaflet your medicine is called Loperamide Tablets. Loperamide hydrochloride is the active ingredient of Loperamide Tablets. The tablets are available in one strength.

Loperamide is one of a group of medicines called "antidiarrhoeals" which are **used to treat diarrhoea**.

Loperamide tablets are used to treat sudden short-lived (acute) attacks of diarrhoea in adults and children aged 9 years and over and long-lasting (chronic) diarrhoea in adults.

The tablets help reduce diarrhoea by slowing down an overactive bowel, which helps the body to absorb water and salts from this organ, making the stools more solid and less frequent.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LOPERAMIDE TABLETS

DO NOT TAKE Loperamide Tablets

- if you are allergic (hypersensitive) to loperamide hydrochloride or any other ingredient of this medicine (listed in section 6).
- if it is for a **child under 9 years old** (or under 18 years old for chronic diarrhoea)
- if you have **acute dysentery**, the symptoms of which may include **blood in your stools** and a **high temperature**.
- if you are having a flare up of an **inflammatory bowel condition** like **ulcerative colitis**
- If you have very smelly stools, blood or pus in your stools, stomach pain, or a fever
- if you have **severe diarrhoea** after taking **antibiotics**
- if you are **constipated** or your **stomach appears swollen** (particularly in children with severe dehydration)

Do not use this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Loperamide Tablets.

Consult a doctor before use if you have a history of drug abuse; loperamide is an opioid and addiction is observed with opioids as a class.

Warnings and precautions

Talk to a doctor or pharmacist before taking Loperamide Tablets:

- if you have **AIDS and your stomach becomes swollen**, stop taking the tablets immediately and contact your doctor.
- if you suffer from **liver problems**.
- if your **diarrhoea lasts for more than 48 hours**.
- if you have **severe diarrhoea**, as your body loses more fluid, sugars and salts than normal.

If any of these applies to you (now or in the past), **talk to a doctor or pharmacist**.

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.

Replacing Fluids and salts

When you have diarrhoea, your body can lose large amounts of fluids and salts. **You will need to replace the fluid by drinking more liquid than usual**. Ask your pharmacist about special powders (known as oral **rehydration therapy**) which replace salts lost during diarrhoea. **This is especially important for children and frail or elderly people**.

Children and adolescents

Short-lived (acute) diarrhoea

The safety and efficacy of Loperamide Tablets in the treatment of short-lived (acute) diarrhoea has not been established in children under 9 years.

Long-lasting (chronic) diarrhoea

The safety and efficacy of Loperamide Tablets in the treatment of long-lasting (chronic) diarrhoea has not been established in children and adolescents under 18 years.

Other medicines and Loperamide Tablets

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

If you are taking any other medicines, including:

- *ritonavir* (used to treat HIV).
- *quinidine* (used to treat abnormal heart rhythms or malaria).
- oral *desmopressin* (used to treat excessive urination).
- any other antidiarrhoeal preparations (except for oral rehydration therapy).
- *itraconazole* or *ketoconazole* (used to treat fungal infections).

If you are unsure about any of the medicines you are taking, show the bottle or pack to your pharmacist.

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.

Do not take Loperamide Tablets if you are breast-feeding as small amounts may get into your milk. Talk to your doctor about suitable treatment.

Driving and using machines

Do not drive if you feel dizzy, tired or sleepy after taking Loperamide Tablets. You may also lose consciousness, feel faint or less alert. If affected do not drive or operate machinery.

Loperamide Tablets contains Lactose

This medicine 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.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodiumfree'.

3. HOW TO TAKE LOPERAMIDE TABLETS

Always take Loperamide Tablets exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The dose of Loperamide Tablets that you will need will depend on whether your diarrhoea is a sudden, short lived attack (acute) or a long-lasting condition (chronic).

- Take this medicine by mouth.
- Swallow the correct number of tablets whole with a drink of water.

Short-lived (acute) diarrhoea

The usual doses are set out in the table below. However, your doctor will advise you what dose to take when you first start taking Loperamide Tablets.

Age	Dose
Adults and children aged 12 and over	Take two tablets to start treatment. Take one tablets after each episode of diarrhoea for up to 5 days . ○ Never take more than eight tablets in a 24-hour period.
Children aged 9-12 years	Take one tablet 4 times daily until diarrhoea is controlled or for up to 5 days . ○ Never take more than this dose.
Children aged under 9 years old	Tablets are not recommended for children under 9 years old. Other pharmaceutical forms/strengths (e.g. syrup) are available for children aged 4 years and over.

If your symptoms are **not getting better within 2 days** of taking your first dose of Loperamide Tablets, you should see your doctor again, who may want to examine you to further check on the cause of the diarrhoea.

Long-lasting (chronic) diarrhoea

Age	Dose
Adults	<p>Your doctor will tell you how much Loperamide Tablets to take.</p> <p>The initial dose will probably be between two and four tablets per day taken in divided doses, but will depend on each individual's needs. When your doctor is satisfied that you are receiving the daily dose that best suits you, he or she will then probably suggest that you take your tablets twice a day.</p> <p>○ Never take more than eight tablets in a 24-hour period.</p>
Children and adolescents aged under 18 years old	NOT recommended.

If you take more Loperamide Tablets than you should

If you or anyone else takes too many Loperamide Tablets, 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 Tablets 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 Tablets

- You should only take this medicine as required 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.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Loperamide Tablets can cause side effects, although not everybody gets them.

Get medical help at once:

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 of the skin.
- Loss of consciousness or reduced level of consciousness (feeling faint or less alert), uncoordinated movements.

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

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

If you get any of these, **stop using the medicine and get medical help at once.**

Talk to a doctor as soon as possible:**Uncommon:** (may affect up to 1 in 100 people)

- Itchiness or hives.
- Stomach pain or severe swollen stomach

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

- Difficulty passing water
- Severe constipation.
- Miosis (narrowing of the pupils of the eye).

If you notice any of the above, stop using the medicine and **talk to a doctor**.

Other effects that may occur:**Common:** (may affect up to 1 in 10 people)

- Feeling sick (nausea), constipation or wind.
- Headache
- Feeling dizzy

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

- Being sick (vomiting), indigestion (dyspepsia)
- Feeling drowsy
- Dry mouth

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

- Tiredness.
- Increased tightness of muscles or increased resistance to passive movement (hypertonia).

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. HOW TO STORE LOPERAMIDE TABLETS

Keep out of the sight and reach of children.

Do not use Loperamide Tablets after the expiry date which is stated on the label or carton after EXP. The expiry date refers to the last day of that month.

Store in the original package.

Do not use this medicine if you notice that the tablets show discolouration or any other signs of deterioration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Loperamide Tablets contain

- The active substance is loperamide hydrochloride. Each tablet contains 2 mg loperamide hydrochloride.
- The other ingredients are maize starch, lactose monohydrate, povidone (K-30), brilliant blue FCF (E133), quinoline yellow (E104), magnesium stearate, talc, colloidal anhydrous silica, sodium starch glycolate and purified water.

What Loperamide Tablets looks like and contents of the pack

Loperamide 2mg Tablets are light green coloured capsule shaped, biconvex uncoated tablets with '2' debossed on one side and score line on other side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Loperamide Tablets are presented in a blister pack of 12 or 30 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder: Torrent
Pharma (UK) Ltd.

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RH10 9BG United

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Manufacturer:

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