

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.

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, or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must contact a doctor if you do not feel better or if you feel worse after 48 hours when treating attacks of acute (short-lived) diarrhoea and attacks of diarrhoea associated with Irritable Bowel Syndrome (IBS).

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
5. How to store **Loperamide Tablets**
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 two types of diarrhoea.

The two types have different age limits.

Short-lived (acute) diarrhoea

- For adults and children aged **12 and over**.
- To treat attacks that last up to **48 hours**.
- If your attack lasts longer than 48 hours, **talk to your doctor**.

IBS diarrhoea

- For adults and young people aged **18 and over** who have been diagnosed with IBS (Irritable Bowel Syndrome).
- To treat attacks that last up to **48 hours**.
- You can use this medicine **for up to 2 weeks** for repeated attacks, but if any one attack lasts continuously for **longer than 48 hours, talk to your doctor**.

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 12 years old (or under 18 for an IBS patient)
- 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**.

Extra warnings for IBS patients

Only take Loperamide to treat acute episodes of diarrhoea associated with Irritable Bowel Syndrome if your doctor has previously diagnosed IBS.

If any of the following apply, do not use the product without first consulting your doctor, even if you know you have IBS:

- if you are **40 years or over** and it is **some time since your last attack of IBS** or **the symptoms are different this time**
- if you have recently **passed blood from the bowel**
- if you suffer from **severe constipation**
- if you are feeling **sick or vomiting**
- if you have **lost your appetite or lost weight**
- if you have **difficulty or pain passing urine**
- if you have a **fever**
- if you have **recently travelled abroad**

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 12 years.

IBS diarrhoea

The safety and efficacy of Loperamide Tablets in the treatment of IBS 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 and sodium

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 'sodium-free'.

3. HOW TO TAKE LOPERAMIDE TABLETS

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

- Swallow the correct number of tablets whole with a drink of water. For oral use only.
- Do not take more than the dose shown in the tables.
- The tablets are not for long-term treatment.

Short-lived (acute) diarrhoea

Age	Dose
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Adults and children aged 12 and over	Take two tablets to start treatment.
	Take one tablets after each loose bowel movement.

- Do not take for attacks lasting **longer than 48 hours**.
 - Do not take more than **six tablets** in a 24-hour period.
-

- Replace lost fluid by drinking more liquid than usual.
 - Not for children aged under 12.
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How long to take Loperamide Tablets for Short-lived (acute) diarrhoea **You can use this medicine for up to 48 hours.**

If your attack lasts longer than 48 hours, stop taking Loperamide Tablets and talk to your doctor.

IBS diarrhoea

Age	Dose
Adults aged 18 and over	Take two tablets to start treatment. Take one tablets after each loose bowel movement (or as advised by your doctor).

- You can use this medicine for up to 2 weeks for repeated attacks, but do not take for any one attack lasting longer than 48 hours.
 - Do not take more than **six tablets** in a 24-hour period.
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- Replace lost fluid by drinking more liquid than usual.
 - Not for children and young people aged under 18.
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Talk to your doctor and stop taking this medicine:

- If you have been using this medicine **continuously for 48 hours**.
- If you develop new IBS symptoms.
- If your IBS symptoms get worse.
- If your IBS symptoms have not improved **after 2 weeks**.

How long to take Loperamide Tablets for IBS diarrhoea

You can use this medicine for up to 2 weeks for repeated attacks of IBS diarrhoea.

But if any one attack lasts for longer than 48 hours, stop taking Loperamide Tablets and talk to your doctor.

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, and most are usually mild.

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 (passing out, feeling faint or less alert), muscle stiffness and uncoordinated movements.

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).

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 swollen stomach.

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

- Difficulties 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, constipation or wind.
- Headache

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

- Dizziness or drowsiness.
- Vomiting, indigestion.
- Dry mouth.

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

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

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. 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 2 mg 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 6 tablets.

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