

370 mm

90 mm

180 mm

Pharmacode Position to be center aligned

46.50 mm



Loperamide Hydrochloride 2 mg Oral Lyophilisate
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 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.

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

The name of your medicine is Loperamide Hydrochloride 2 mg Oral Lyophilisate (called Loperamide in this leaflet). Loperamide is one of a group of medicines called "anti-diarrhoeals" which are used to treat diarrhoea by slowing down an overactive bowel. This allows water and salts that are usually lost in diarrhoea to be absorbed by the body.

Loperamide is used to treat two types of diarrhoea. The two types have different age limits.

- **Short-term 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.
- **Irritable Bowel Syndrome (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.

2. What you need to know before you take Loperamide

Do not take Loperamide, if:

- you are allergic to loperamide or any other ingredient in this product (listed in section 6);
- it is for a child aged under 12 (or under 18 for an IBS patient);
- you have severe diarrhoea after taking antibiotics;
- you are having a flare-up of an inflammatory bowel condition like ulcerative colitis;
- you are constipated, or your stomach appears swollen (especially in children with severe dehydration);
- you have acute dysentery, the symptoms of which may include blood in your stools and a high temperature.

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

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 tablets immediately and see your doctor immediately;
- you suffer from liver disease;
- you have diarrhoea that lasts for more than 48 hours;
- you have severe diarrhoea as your body loses more fluid, sugars and salts than normal.

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

Other medicines and Loperamide

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.
- Do not take Loperamide if you are breast-feeding as small amounts of the medicine may get into your milk. You should talk to your doctor about suitable treatment.

Driving and using machines

These tablets may cause dizziness, sleepiness or tiredness. 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 2 mg of Loperamide. 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

Special warnings about this medicine

- Your body can lose large amounts of fluids and salts when you have diarrhoea. You need to replace the fluid by drinking more liquid than usual. Ask your pharmacist about rehydration therapy to replace lost salts. This is especially important for children, and frail or older people.
- 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 hydrochloride.
- Loperamide is a type of opioid that acts directly on the gut when used as recommended but can cause other opioid effects when misused at high doses. Addiction is observed with opioids as a class.

Extra warnings for IBS patients: Use only if your doctor has previously diagnosed IBS.

If any of these applies to you, **talk to your doctor or pharmacist first** before taking the medicine, if you;

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

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.



Pack Insert
Dimension: 180 x 370 mm

Substrate: 40 GSM Bible Paper

Front Side

370 mm

180 mm

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

- Peel back the lid and tip the tablet out. Do not push the tablets through the lid.
- Place the correct number of tablets on the tongue. The tablets 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 tablets are not for long-term treatment.

Short-term diarrhoea

Age	Dose
Adults and children aged 12 and over	Take two tablets to start treatment. Take one tablet after each loose bowel movement.
<ul style="list-style-type: none">● Do not take for attacks lasting longer than 48 hours.● Do not take more than six tablets in a 24-hour period.	
<ul style="list-style-type: none">● <i>Replace lost fluid by drinking more liquid than usual.</i>● Not for children aged under 12.	

How long to take Loperamide for short-term diarrhoea

You can use this medicine for up to 48 hours.
If your attack lasts longer than 48 hours, stop taking Loperamide and talk to your doctor.

IBS diarrhoea

Age	Dose
Adults aged 18 and over	Take two tablets to start treatment. Take one tablet after each loose bowel movement.
<ul style="list-style-type: none">● Do not take for attacks lasting longer than 48 hours.● Do not take more than six tablets in a 24-hour period.	
<ul style="list-style-type: none">● 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.	
<ul style="list-style-type: none">● <i>Replace lost fluid by drinking more liquid than usual.</i>● Not for children and young people aged under 18.	

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 you take more Loperamide than you should

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, difficulty urinating, or weak breathing.

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 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.

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, most are usually mild.

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.
- Hypertonia (muscle tension).
- Coordination abnormality (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.**

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist . This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme on the MHRA website 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

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

Store in the original package to protect from moisture. The medicinal product does not require any special temperature 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 Loperamide 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, E1450).

What Loperamide looks like and contents of the pack

Oral

White to off-white, round, lyophilised tablets, debossed with T on one side and available in blister pack containing 6 tablets, 12 tablets (6 tablets per blister strip) in an outer carton.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

RxFarma,
Colonial Way, Watford, Hertfordshire,
WD24 4YR

Manufacturer

Rx Farma Limited,
Unit 3, Colonial Way, Watford, Hertfordshire,
WD24 4YR, United Kingdom

This leaflet was last revised in 08/2025.

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Pack Insert
Dimension: 180 x 370 mm

Substrate: 40 GSM Bible Paper

Back Side