

PHARMACODE

Package leaflet: Information for the user

Loperamide hydrochloride 2 mg Orodispersible 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 have 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 talk to a doctor if you do not feel better or if you feel worse after 2 days.

This medicine is used for two different types of diarrhoea. They have **different age limits**. See section 1.

Do not take this medicine

- There are some people who **should not use this medicine**. To find out if you are one of them, see section 2.
- If you have ever had a bad reaction to any of the ingredients. For the list of ingredients see section 6.

Speak to your doctor

- If you suffer from any of the conditions mentioned in section 2.
- If you are taking any other medicines. See section 2.

If you have **Irritable Bowel Syndrome (IBS)** see section 2 'Extra warnings for IBS patients'.

Follow the dosage instructions carefully. See section 3.

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

What is in this leaflet:

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

1. What Loperamide Orodispersible Tablets are and what they are used for

Loperamide hydrochloride 2 mg Orodispersible Tablets are 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**.

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 contain loperamide hydrochloride, a substance that helps reduce diarrhoea by slowing down an overactive bowel. This allows water and salts that are usually lost in diarrhoea to be absorbed by the body.

2. What you need to know before you take Loperamide Orodispersible Tablets

This medicine is suitable for most people, but a few people should not use it.

Do not take Loperamide Orodispersible Tablets

- If you have ever had a **bad reaction** to any of the ingredients
- If it is for a child under 12 years of age (or under 18 for an IBS patient)
- If you have **severe diarrhoea** after taking **antibiotics**
- If you are having a flare-up of an **inflammatory bowel condition** like **ulcerative colitis**
- If you are **constipated**, or your **stomach appears swollen** (especially in children with severe dehydration)
- If you have **acute dysentery**, the symptoms of which may include **blood in your stools** and a **high temperature**.

If any of these apply to you, **talk to a doctor or pharmacist and do not take Loperamide Orodispersible Tablets**.

Warnings and precautions

Talk to your doctor before taking Loperamide Orodispersible Tablets:

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

Other medicines and Loperamide Orodispersible Tablets

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

- 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 unsure about any of the medicines you are taking, show the pack to your pharmacist. If any of these apply to you, **talk to a doctor or 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.

If you are breast-feeding, do not take this medicine. 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 feel less alert, feel faint, or pass out. If you're affected do not drive, cycle or use machines.

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.**
- 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.
- 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.
- Abuse and misuse of loperamide, the active ingredient in Loperamide Orodispersible Tablets, have been reported. 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 Orodispersible Tablets.

Loperamide Orodispersible Tablets contain sodium

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

For acute episodes of diarrhoea associated with irritable bowel syndrome (IBS)

You should only use this medicine to treat acute episodes of diarrhoea associated with IBS if your doctor has told you that you suffer from IBS.

If you are taking loperamide for episodes of IBS you should stop taking the medicine if you do not get better within 48 hours or if the pattern of your symptoms change or repeated episodes of diarrhoea continue for more than 2 weeks.

If this is the first time you have had these symptoms talk to your doctor before using this medicine. This is to make sure it is suitable for you.

Do not use this medicine without talking to your doctor if you:

- Are over 40 years of age
- Have passed blood in your stools or motions
- Are feeling sick or being sick
- Have lost your appetite or lost weight
- Look pale or feel tired
- Are very constipated
- Have a fever
- Have recently been travelling abroad
- Are or may be pregnant
- Have abnormal vaginal bleeding or discharge
- Have difficulty or pain when passing water

Talk to your doctor if you get new symptoms, your symptoms get worse or if they do not improve after 2 weeks of treatment.

3. How to take Loperamide Orodispersible Tablets

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

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

- Check the foil is not broken before use. If it is, do not take that tablet.
- With dry hands take the tablet from the foil and place immediately on the tongue.
- The tablets, which are "melt in the mouth" spearmint flavoured tablets, are designed to be placed on the tongue and allowed to completely disintegrate before swallowing.
- The tablets will normally disintegrate in the mouth in contact with saliva, therefore water or other liquids are not normally needed in order to take the tablets.
- You may need to drink more fluid than usual when you have diarrhoea as fluids may be lost in the stools.
- Do not use more than the dose shown in the tables.
- The tablets are not for long-term treatment.

Acute diarrhoea	
Age	Dose
Adults and children aged 12 years and over.	Take two tablets to start treatment. Take one tablet 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 years.

How long to take Loperamide Orodispersible Tablets for acute diarrhoea

You can use this medicine for up to 48 hours.

If you are taking loperamide for acute diarrhoea you should stop taking the medicine and talk to your doctor if you do not get better within 48 hours.

Size: 210 x 360 mm

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For acute episodes of diarrhoea associated with Irritable bowel syndrome (IBS)

Age	Dose
Adults aged 18 years and over	Take two tablets to start treatment. Take one tablet 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.
- Replace lost fluid by drinking more liquid than usual.
- Not for children and young people under 18 years of age.

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 Orodispersible 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 Orodispersible Tablets and **talk to your doctor**.

If you take more Loperamide Orodispersible Tablets than you should

If you have taken too many Loperamide Orodispersible 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 Orodispersible 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 Orodispersible Tablets

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.

4. Possible side effects

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

Stop taking Loperamide Orodispersible Tablets and contact your doctor immediately if you experience any of the following:

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), 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**.

If you experience any of the following stop taking Loperamide Orodispersible Tablets and talk to your 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)
- Hypertonia (muscle tension)
- Coordination abnormality (uncoordinated movements)

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

Other effects that may occur

Common (may affect up to 1 in 10 people)

- Headache
- Feeling sick, constipation or wind

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

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 Orodispersible Tablets

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from moisture. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measurements will help protect the environment.

6. Contents of the pack and other information

What Loperamide Orodispersible Tablets contain

The active ingredient in Loperamide Orodispersible Tablets is loperamide hydrochloride.

Each tablet contains 2 mg of loperamide hydrochloride.

The other ingredients are:

Mannitol (E421), Cellulose microcrystalline, Aspartame powder, Crospovidone (E1202), Croscarmellose sodium (E468), Citric acid anhydrous (E330), Silica colloidal anhydrous (E551), Spearmint flavour (corn maltodextrin, flavouring preparation, acacia gum, nature-identical flavouring substance), Talc and Magnesium stearate (E572).

What Loperamide Orodispersible Tablets look like and contents of the pack

Orodispersible tablets.

Approximately 7 mm in diameter, white to off white, circular, flat faced, bevelled edged, uncoated tablets, plain on both sides.

PVC/Aluminium/OPA laminate with aluminium lidding foil blister containing 6 tablets. PVDC coated PVC film with aluminium lidding foil blister containing 6 tablets.

Pack sizes: 6 & 12 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

DAWA Limited
5 Sandridge Close
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Manufacturer:

Drugsrus Limited
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This leaflet was last updated in May 2025.

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