

Package leaflet: Information for the user

Loperamide 2 mg Tablets

loperamide hydrochloride

Read all of this leaflet carefully before you start using 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 Tablet** is and What it is used for
2. What you need to know before you use **Loperamide Tablets**
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1. What Loperamide Tablet is and What it is used for

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 2 mg 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 use Loperamide Tablets

Do not use Loperamide Tablets

- if you are **allergic** to loperamide hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- if you have **severe diarrhea** 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** (particularly in children with severe dehydration)
- if you have **acute dysentery**, the symptoms of which may include blood in your stools and a high temperature.

Do not give this medicine to a child under 9 years old.

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.

Warnings and precautions

Talk to your 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 you have **severe diarrhoea** as your body loses more fluid, sugars and salts than normal.
- if you have diarrhoea that lasts for more than 48 hours.

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

Special warnings:

- Loperamide only treats the symptoms of diarrhoea. 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.** This is especially important for children. Ask your pharmacist about special powders (known as oral rehydration therapy) which replace fluids and salts lost during diarrhoea. The prevention of fluid depletion (dehydration) is of particular importance in infants, children and frail and elderly people with acute diarrhoea.

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 Tablet.

Other medicines and Loperamide Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. In particular, tell your doctor or pharmacist if you are taking any of the following:

- ritonavir (used to treat HIV)
- quinidine (used to treat abnormal heart rhythms or malaria)
- itraconazole, ketoconazole (used to treat fungal infections)
- gemfibrozil (used to reduce levels of cholesterol)
- oral desmopressin (used to treat excessive urination)
- other drugs that slow down or speed up movement in the gut

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 this medicine 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 this medicine. You may also lose consciousness, feel faint or less alert. If affected do not drive or operate machinery.

Loperamide Tablets 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 use Loperamide Tablets

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist 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.
- The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

Short-lived (acute) diarrhoea

Adults and children over 12 years:

- Take **two tablets** to begin with and then **one tablet** after each episode of diarrhoea for up to 5 days.
- Never take more than 8 tablets in any 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:

This medicine should not be given to 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 this medicine, you should see your doctor again, who may want to examine you to further check on the cause of the diarrhoea.

Long-lasting (chronic) diarrhea

Adults only:

- Your doctor will tell you how much Loperamide tablets to take.
- 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.
- Never take more than 8 tablets in any 24 hour period.

If you take more Loperamide Tablets than you should

If you have taken 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, reduction in size of the pupils in the eye (miosis), constipation and a condition where the bowel does not work properly (ileus). 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 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 medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Stop using Loperamide tablets and tell your doctor straight away if you notice or suspect any of the following. You may need urgent medical treatment.

- Sudden swelling of the face lips, or throat.
Hives (also known as nettle rash or urticaria).
Severe irritation, reddening or blistering of your skin.
These may be signs of a severe allergic reaction
- Blistering of your skin, mouth, eyes or genitals

- Stomach pain or severe swollen stomach
- Severe constipation
- Loss of consciousness or reduced level of consciousness (feeling faint)

Tell your doctor if you notice any of the following side effects while using Loperamide Tablets:

Common side effects (may affect up to 1 in 10 people)

- Headache
- Feeling sick (nausea)
- Constipation
- Wind

Uncommon side effects (may affect up to 1 in 100 people)

- Feeling sleepy or drowsy
- Dry mouth
- Being sick (vomiting), indigestion (dyspepsia)
- Rash
- Abdominal pain or discomfort
- Feeling dizzy

Rare side effects (affects fewer than 1 in 1000 patients)

- Tiny pupils
- Itchy skin
- Difficulty passing water
- Feeling tired
- Problems with co-ordination
- Unusually stiff muscles causing poor control of movement
- Burning, tingling mouth (glossodynia)

Some of the listed side effects may be due to the diarrhoea, such as discomfort around the middle, feeling sick or being sick, dry mouth, feeling tired, drowsy or dizzy and wind.

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 this medicine out of the sight and reach of children.

Do not use this medicine 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.

If the tablets become discoloured or show any other signs of deterioration, consult your pharmacist who will tell you what to do.

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 Tablets contains

- 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 and sodium starch glycolate and purified water.

What Loperamide Tablets looks like and contents of the pack

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

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

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

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

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