

Loperamide

2mg Tablets

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.
- You must contact a doctor if your symptoms worsen or do not improve after 2 (two) days.
- 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 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 2mg Tablets (called Loperamide Tablets in this leaflet). The active ingredient is loperamide hydrochloride. It belongs to a group of medicines which helps reduce diarrhoea by slowing down an overactive bowel. It also helps the body to absorb more water and salts from the bowel.

Loperamide Tablets are used to treat sudden short-lived (acute) attacks of diarrhoea in adults and children over 6 years of age and for the treatment of long-lasting (chronic) diarrhoea in adults.

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

Do not take Loperamide Tablets

- If you are allergic to loperamide or any of the other ingredients of this medicine (listed in section 6).
- If you have severe diarrhoea after taking antibiotics.
- If you are having a flare up of ulcerative colitis.
- If you have acute dysentery, the symptoms of which may include blood in your stools and a high temperature.
- If you are constipated or your stomach appears swollen (particularly in children with severe dehydration).
- If you (your child) is less than 6 years old (see section 3 of this leaflet for more information).

Warnings and precautions

Talk to your doctor or pharmacist before taking Loperamide Tablets if:

- You suffer from liver problems.
- You have AIDS and your stomach becomes swollen. Stop taking the tablets immediately and contact your doctor.
- You have an intolerance to some sugars.
- You have acute diarrhoea and are not getting better within 2 days of taking your first dose of Loperamide Tablets, stop taking the tablets and go back to your doctor.

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.

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 Tablets.

Replacing fluid and salts

Loperamide Tablets only treat the symptoms of diarrhoea. When you have diarrhoea, your body loses large amounts of fluid and salts. You should therefore replace this lost fluid by drinking more than normal. This is especially important for children.

Your doctor may also give you a special powder containing sugar and salts (known as oral rehydration therapy) to help your body replace the fluid and salts lost during diarrhoea.

Other medicines and Loperamide Tablets

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

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),
- oral desmopressin (used to treat excessive urination),
- itraconazole or ketoconazole (used to treat fungal infections),
- gemfibrozil (used to control cholesterol levels in your blood).

Loperamide Tablets with food, drink and alcohol.

Loperamide Tablets can be taken with or without food. Drinking extra fluids is recommended while you have diarrhoea. Check with your doctor if you have questions. Alcohol should be avoided as loperamide may cause drowsiness or dizziness and alcohol may intensify these effects.

Pregnancy and breast-feeding

If you are pregnant, 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 a suitable treatment.

Driving and using machines

This medicine may make you feel dizzy, tired or sleepy. If affected do not drive or operate machinery.

Loperamide Tablets contain lactose

Loperamide Tablets contain lactose. If your doctor has told you that you are **intolerant of some sugars**, discuss it with them before taking this medicine.

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 this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take this medicine by mouth. Swallow the correct number of tablets with a drink of water. The break line is to facilitate breaking for ease of swallowing.

Short-lived (acute) diarrhoea

Adults and children over 6 years: Take 2 (two) tablets straight away. From then on take 1 (one) tablet after each episode of diarrhoea. You can take this medicine for up to 5 days. **Never take more than 8 tablets in any 24 hour period**

Children between 2 and 5 years old: Loperamide Tablets are not recommended for children between 2 and 5 years old. Your doctor may recommend a different formulation, such as an oral solution which is more suitable for children.

If you are not getting better within 2 days of taking your first dose of Loperamide Tablets, go back to your doctor. He or she may want to examine you to check on why you have diarrhoea.

Long-lasting (chronic) diarrhoea

Adults: Your doctor will tell you how many Loperamide Tablets to take. This will depend on how serious your condition is. You will probably start with a dose of between 2 (two) and 4 (four) tablets spread out over a day. Your doctor will find the dose that suits you best. He or she may then suggest you take the tablets twice a day. **Never take more than 8 tablets in any 24 hour period.**

Children: Loperamide Tablets are not recommended for long-lasting (chronic) diarrhoea.

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. 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 stop taking Loperamide Tablets

Your doctor can judge best when and how you must stop taking Loperamide Tablets. Always contact your doctor before you want to stop taking the medicine.

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

4. Possible side effects

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

Get medical help at once:

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).

Stop taking 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 and genitals.
- Stomach pain or severe swollen stomach.
- Severe constipation.

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
- Dizziness
- Constipation
- Nausea (feeling sick)
- Flatulence (passing wind)

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

- Feeling sleepy
- Abdominal pain/discomfort
- Dry mouth
- Vomiting
- Indigestion
- Rash

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

- Hypersensitivity reaction
- Serious allergic reaction which causes difficulty in breathing or dizziness
- Loss or decreased level of consciousness
- Abnormal increase in muscle tension
- Coordination abnormality
- Constriction of the pupils of the eyes
- Partial or complete blockage of the small/large intestine
- Rapid widening of the large intestine
- Abdominal swelling
- Swelling/burning sensation of the tongue/mouth
- Blisters and skin lesions (including Stevens-Johnson syndrome, Toxic epidermal necrolysis and Erythema multiforme)
- Swelling of the deeper layers skin (Angioedema)
- Hives (urticaria)
- Itchy skin (pruritus)
- Lack of ability to urinate (urinary retention)
- Fatigue

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 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.

This medicine does not require any special storage conditions. If the tablets become discoloured or show any other signs of deterioration, consult your pharmacist who will tell you what to do.

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

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 contain

The active substance is loperamide, each tablet contains 2 mg loperamide as loperamide hydrochloride.

The other ingredients are lactose monohydrate, maize starch, talc, magnesium stearate, povidone, brilliant blue (E133), quinoline yellow (E104), colloidal anhydrous silica and sodium starch glycolate.

What Loperamide Tablets look like and contents of the pack

Light green coloured, capsule shaped, biconvex uncoated tablets, plain 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 available in blister packs of 30 tablets.

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