



PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Loperamide Hydrochloride 2mg
Capsules



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 or pharmacist 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 talk to a doctor if you do not feel better or if you feel worse after 48 hours

What is in this leaflet:

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1 What Loperamide is and what it is used for

Loperamide Hydrochloride belongs to a group of medicines called 'antidiarrhoeals' which are used to treat diarrhoea. It 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.

Loperamide is used to treat:

- short-lived (acute) attacks of diarrhoea
- sudden short lived (acute) attacks of diarrhoea in adults and children over 12 years of age
- episodes of diarrhoea in adults and young people aged 18 and over who have been diagnosed with Irritable Bowel Syndrome (IBS)

For IBS diarrhoea, 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 of the other ingredients of this medicine (listed in section 6)
- It is for a child aged under 12 (or under 18 for an IBS patient)
- You need to keep the bowel movements normal to avoid complications such as blockage of the bowel and abnormal or rapid widening of the colon
- You have constipation, blockage of the bowel or a bloated tummy
- You have a flare-up of ulcerative colitis (a form of inflammatory bowel disease) which can cause abdominal pain, bloody diarrhoea, fever and weight loss
- You have severe diarrhoea after taking antibiotics (symptoms may include watery or bloody diarrhoea)
- You have a bacterial infection of the small intestine and colon (caused by bacteria such as salmonella, shigella and campylobacter)
- You have inflammation of the colon after taking antibiotics the symptoms of which may include watery or bloody diarrhoea
- You have acute (short-lived) dysentery, the symptoms of which may include blood in your stools and a high temperature

Warnings and precautions

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.

Stop taking Loperamide and talk to your doctor if there is no improvement in your symptoms within 48 hours

Talk to your doctor before taking Loperamide if:

- You have or think you may have lost body fluids and salts through diarrhoea. Particularly important for children and frail or elderly patients with severe diarrhoea (see 'Replacing fluids and salts', section 3)
- You have liver disease. You should consult your doctor or pharmacist before taking Loperamide as it may cause side effects

- You are taking Loperamide to treat diarrhoea caused by Irritable Bowel Syndrome (IBS). See "Special warnings for IBS patients" section
- You have a bloated tummy and you have AIDS. You should stop taking the capsules immediately and contact your doctor

Special warnings for IBS patients

Only take this medicine to treat episodes of diarrhoea associated with Irritable Bowel Syndrome if your doctor has previously diagnosed IBS. If any of the following apply, do not use this medicine without first consulting your doctor, even if you know you have IBS:

- If you are aged 40 or over and it is some time since your last IBS attack
- If you are aged 40 or over and your IBS 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

Consult your doctor if you develop new symptoms, or if your symptoms worsen, or your symptoms have not improved over two weeks.

Other medicines and Loperamide

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

Loperamide should **not be taken** with the following:

- Other antidiarrhoea preparations, except for oral rehydration therapy (see "Replacing fluids and salts" in section 3)

Loperamide **may cause serious side effects** if taken with the following:

- Quinidine, for abnormal and increased heart rhythm
- Ritonavir, for HIV infection and AIDS
- Itraconazole and Ketoconazole, for fungal infections
- Gemfibrozil, used to lower levels of cholesterol and other lipids (fats) in the blood

Loperamide **increases the blood levels** of the following:

- Oral desmopressin, for reducing urine production (antidiuretic)

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 for advice before taking this medicine.

Pregnancy

If you are pregnant or planning to become pregnant, you are advised not to take Loperamide. It is not known if it is safe to take, especially during the first 3 months of pregnancy.

Breast-feeding

If you are breast-feeding, you should not take Loperamide, as small amounts of this medicine get into your breast milk.

Driving and using machines

This medicine may make you feel tired, dizzy or drowsy. You may feel less alert, feel faint or pass out. If affected, you are advised not to drive or operate machinery.

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Hard to Read?
Phone 0800 970 6115 for help



Loperamide contains Lactose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

Loperamide contains colouring agent Sunset Yellow FCF (E110)
It may cause allergic reaction.

3 How to take Loperamide

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

- Loperamide is for oral use only
- Swallow the capsules whole with some liquid

Short-term diarrhoea

Adults and children over 12 years:

- 2 capsules (4mg) initially, followed by 1 capsule (2mg) after each loose stool (bowel movement)
- The maximum dose is 6 capsules (12mg) in 24 hours

Diarrhoea associated with Irritable Bowel Syndrome

Adults aged 18 years and over:

- 2 capsules (4mg) initially, followed by 1 capsule (2mg) after each loose stool, or as previously advised by your doctor
- The maximum dose is 6 capsules (12mg) in 24 hours
- For IBS diarrhoea, you can use this medicine for up to 2 weeks for repeated attacks, but do not use if any one attack lasts continuously for longer than 48 hours and talk to your doctor

Patients with liver problems

See 'Warnings and precautions' (section 2)

Use in children under 12 years:

This medicine should not be given to children under 12 years of age.

If you have diarrhoea and your symptoms do not improve within 48 hours, you should stop taking Loperamide and contact your doctor.

Replacing fluids and salts

When you have diarrhoea, your body loses large amounts of fluid and salts. In addition to your medicine, you should take more liquids than normal. Drink plenty of clear fluids containing salt and sugar (special oral rehydration powders are available from pharmacists). This is especially important for children, and frail or elderly people.

If you take more Loperamide than you should

If you have taken too many capsules, immediately contact a doctor or hospital for advice. Remember to take this leaflet or any remaining capsules with you.

Symptoms (of an overdose) 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

Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose, 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 Loperamide can cause side effects, although not everybody gets them.

Seek medical advice immediately if you develop the following (rare) symptoms:

- Bloating tummy which may be due to enlargement of the large intestine, which may cause constipation, bloating and tenderness of the stomach or fever (megacolon or toxic megacolon)
- Allergic reaction: swelling of the face, throat or tongue, difficulty breathing (anaphylaxis) and dizziness

- Severe blistering of the skin, mouth, eyes and genitals (Steven-Johnson's Syndrome or toxic epidermal necrolysis)
- Fever, general ill feeling, itching, joint aches, multiple skin lesions (erythema multiforme)
- Swelling of the deeper layers of the skin caused by a build-up of fluid (angioedema)
- Loss of consciousness or reduced level of consciousness (passing out, feeling faint or less alert)
- Difficulty co-ordinating movement
- Difficulty in urinating (passing water)
- Severe constipation
- Blockage of the bowel

Common side effects

(may affect up to 1 in 10 people)

- Headache
- Constipation
- Feeling sick (nausea)
- Stomach wind (flatulence)

Uncommon side effects

(may affect up to 1 in 100 people)

- Dizziness
- Drowsiness
- Stomach pain or discomfort
- Dry mouth
- Being sick (vomiting)
- Indigestion
- Rash

Rare side effects

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

- Abnormal increase in muscle tension
- Pupils of the eyes become smaller
- Bloating tummy
- Skin rashes with the formation of wheals
- Severe itching
- Tiredness (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

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Store in the original package in order to protect from light.
- Do not use this medicine after the expiry date, which is stated on the carton/blister 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 to protect the environment.

6 Contents of the pack and other information

What Loperamide contains:

Each capsule contains 2mg of Loperamide Hydrochloride.

The other ingredients are:

Lactose, maize starch, talc, magnesium stearate, gelatin, colouring agents sunset yellow FCF (E110), erythrosine (E127), patent blue (E131), indigotine (E132) and titanium dioxide (E171). (see " Loperamide contains Lactose and colouring agent Sunset Yellow FCF (E110)" in section 2)

What Loperamide looks like and the contents of the pack:

Loperamide are grey-dark green coloured hard gelatin size 3 capsules, filled with a homogeneous white to off white powder.

Loperamide is available in:

Loperamide is available in packs of 8, 10, 12, 18 or 30 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder & Manufacturer:

Tillomed Laboratories Ltd,
220 Butterfield, Great Marlings,
Luton, LU2 8DL, UK

Legal category:

Pharmacy Medicine (P)

Product Licence Number:

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