

Package leaflet: Information for the patient

Loperamide 2mg Capsules (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 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, 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 capsules are and what they are used for
2. What you need to know before you take Loperamide capsules
3. How to take Loperamide capsules
4. Possible side effects
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6. Contents of the pack and other information

1. WHAT LOPERAMIDE CAPSULES ARE AND WHAT THEY ARE USED FOR

The capsules 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. It works by making the stools more solid and less frequent.

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

Short-term (acute) diarrhoea

- For adults and children aged 12 years and over
- To treat attacks that last up to 48 hours
- If your attack lasts longer than 48 hours, talk to your doctor.

IBS (irritable bowel syndrome) diarrhoea

- For adults and young people aged 18 years and over who have been diagnosed with IBS
- 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 CAPSULES

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

Do not take Loperamide capsules:

- If you have ever had a bad (allergic) reaction to loperamide or to any of the other ingredients (listed in section 6)
- If it is for a child aged under 12 (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.

Warnings and precautions:

Talk to your doctor or pharmacist first before taking this medicine:

- If you have a history of drug abuse; loperamide is an opioid and addiction is observed with opioids as a class.
- If you suffer from liver problems
- If you have diarrhoea that has lasted for more than 48 hours
- If you have severe diarrhoea as your body loses more fluid, sugars and salts than normal.

Taking other medicines

Talk to your doctor or pharmacist before taking this medicine if you are taking any other medicines, including:

- 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 bottle or pack to your pharmacist.

Pregnancy or breast-feeding

- If you are pregnant, think you are pregnant or planning a pregnancy: 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 or use machines.

Other Special warnings

If you have AIDS and your stomach becomes swollen, stop taking the capsules immediately and contact your doctor

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.

Never take more than the recommended dose (see Section 3), as serious heart problems have been reported in people who have taken too much loperamide (symptoms include fast or irregular heartbeat).

Information about some of the ingredients which can cause problems

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicine.

The capsule shells contain Sunset Yellow (E110) and Carmoisine (E122) which may cause allergic reactions. This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

Extra warnings for IBS patients

Only take Loperamide Capsules to treat sudden attacks of diarrhoea associated with IBS, if your doctor has previously diagnosed you with IBS.

Do not take this medicine for IBS:

- If you are aged under 18 years.

Talk to your doctor first:

- 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.

If any of these applies to you, talk to your doctor before taking Loperamide capsules.

3. HOW TO TAKE LOPERAMIDE CAPSULES

Swallow the capsules whole with a drink of water. For oral use only.

Do not take more than the doses given below.

The capsules are not for long-term treatment.

Short term diarrhoea

Adults and children aged 12 and over:

- Take two capsules to start treatment
- Take one capsule after each loose bowel movement
- Do not take more than six capsules in a 24-hour period and do not take for longer than 48 hours
- Replace lost fluid by drinking more liquid than usual
- Not to be taken by children aged under 12.

IBS diarrhoea

Adults aged 18 and over only:

- Take two capsules to start treatment
- Take one capsule after each loose bowel movement (or as advised by your doctor)
- Do not take more than six capsules in a 24-hour period
- 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
- Replace lost fluid by drinking more liquid than usual
- 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 for IBS continuously for 48 hours, if you develop new IBS symptoms, if your symptoms get worse or have not improved after 2 weeks.

If you take more Loperamide capsules than you should

If anyone takes too many Loperamide capsules, contact your doctor or nearest Accident and Emergency department taking this leaflet with you. Serious heart problems (potentially with life-threatening consequences) have been reported with loperamide overdose, symptoms include fast or irregular heartbeat. Other symptoms of overdose include muscle stiffness, uncoordinated movements, drowsiness, difficulty urinating and weak breathing.

If you forget to take Loperamide capsules

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.

If you get any of the following rare side effects, stop taking the capsules and seek medical help immediately:

- Allergic reactions including unexplained wheezing, shortness of breath, passing out, swelling of the face, tongue or throat
- Severe skin rashes and blistering or peeling skin
- Loss of consciousness or reduced level of consciousness (passing out, feeling faint or less alert), uncoordinated movement

See your doctor as soon as possible if you get any of the following effects:

Uncommon: (affects less than 1 in 100 people)

- Itchiness or hives
- Stomach pain or swollen stomach.

Rare: (affects less than 1 in 1,000 people)

- Difficulties passing water
- Severe constipation
- Miosis (narrowing of the pupils of the eye).

Check with your doctor or pharmacist if you get any of the following other side effects that may occur:

Common: (affects less than 1 in 10 people)

- Feeling sick, constipation or wind
- Headache.

Uncommon: (affects less than 1 in 100 people)

- Dizziness or drowsiness
- Rash
- Vomiting, indigestion, abdominal pain or discomfort
- Dry mouth.

Rare: (affects less than 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 THIS MEDICINE

Keep this medicine out of the sight and reach of children.

Do not store above 30°C. Store in the original package.

Do not use this medicine after the expiry date which is stated on the packaging.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Loperamide Capsules contain:

Each capsule contains Loperamide hydrochloride 2 mg as the active ingredient.

Other ingredients are: Lactose monohydrate, maize starch, talc, magnesium stearate and the capsule shells contain gelatin, patent blue (E131), quinoline yellow (E104), sunset yellow (E110), carmoisine (E122), titanium dioxide (E171), sodium laurilsulfate.

What Loperamide Capsules look like and the contents of the pack

Loperamide Capsules are Green/Mauve coloured capsules. Pack sizes of 18 or 30 capsules.

Marketing Authorisation Holder:

RxFarma

Colonial Way,

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Manufacturer:

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If you would like this leaflet in a different format, please contact the MA holder at the address above.

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