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Package leaflet: Information for the patient

Loperamide Hydrochloride 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 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 24 hours.

What is in this leaflet?

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

1. What Loperamide is and what it is used for

Loperamide is 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 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.

2. What you need to know before you take Loperamide

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

Do not take Loperamide, if

- you are **allergic** to loperamide hydrochloride 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 have **severe diarrhoea** after taking **antibiotics**.
- you are having a flare-up of an **inflammatory bowel condition** like **ulcerative colitis**.
- you are **constipated**, or your **stomach appears swollen** (especially in children with severe dehydration).
- you have **acute dysentery**, the symptoms of which may include **blood in your stools** and a **high temperature**.

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Loperamide, if you

- have **AIDS** and your **stomach becomes swollen**, stop taking the capsules immediately and contact your doctor.
- suffer from **liver disease**.
- have diarrhoea that lasts for **more than 48 hours**.
- have been told by your doctor that you have **intolerance to some sugars**.
- have **severe diarrhoea** as your body loses more fluid, sugars and salts than normal.

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 with a doctor if you have a history of drug abuse.
- 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 Hydrochloride 2mg Capsules, 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 Hydrochloride 2mg Capsules.

Extra warnings for IBS patients

Use only if your doctor has previously diagnosed IBS.

Check the following:

Do not take this medicine

- If you are aged **under 18**.

Talk to your doctor first, if you

- are aged **40 or over** and it is **some time since your last IBS attack**.
- are aged **40 or over** and your **IBS symptoms are different** this time.
- have recently **passed blood from the bowel**.
- suffer from **severe constipation**.
- are feeling **sick or vomiting**.
- have **lost your appetite or lost weight**.
- have **difficulty or pain passing urine**.
- have a **fever**.
- have **recently travelled abroad**.

Other medicines and Loperamide

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially 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 treat **high cholesterol**).

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

If any of these applies to you (now or in the past), **talk to a doctor or pharmacist**.

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.
- **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.

Loperamide hydrochloride 2mg capsule contains Lactose: 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.

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.

3. How to take Loperamide

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.

The dose of Loperamide that you will need will depend on whether your diarrhoea is a sudden, short-lived attack (acute) or a long-lasting condition (chronic or IBS).

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

- Swallow the correct number of capsules whole with a drink of water. For oral use only.
- The capsules are **not for long-term treatment**.
- Do not use more than the recommended dose.

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Short-term diarrhoea

Age	Dose
Adults (including Elderly) and children aged 12 years and over	Take two capsules to start treatment Take one capsule after each loose bowel movement.

- Do not take for attacks lasting **longer than 48 hours**.
- Do not take more than **six capsules** in a 24-hour period.
- Replace lost fluid by drinking more liquid than usual.*
- Not recommended for children aged under 12.

You can use this medicine for up to 48 hours.
If your attack lasts longer than 48 hours, stop taking Loperamide and **talk to your doctor**.

IBS diarrhoea

Age	Dose
Adults aged 18 and over	Take two capsules to start treatment. Take one capsule 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 capsules** in a 24-hour period.
- Replace lost fluid by drinking more liquid than usual*
- Not recommended for children and young people aged under 18

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**.

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 and **talk to your doctor**.

If you take more Loperamide than you should
If you have taken too many Loperamide 2mg Hydrochloride capsules, 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 Hydrochloride capsules 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
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.

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.

Get medical help at once

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**.

Talk to a 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 the medicine and **talk to a doctor**.

Other effects that may occur

Common: (may affect up to 1 in 10 people)

- Feeling sick, constipation or wind.
- Headache.

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

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 carton or label after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 contains
The active substance is Loperamide Hydrochloride. Each capsule contains 2mg Loperamide Hydrochloride.

Other ingredients are:
Lactose.
The capsule shell contains Brilliant Blue (E133), Iron Oxide (E172), Titanium Dioxide (E171), Purified water and Gelatin.

What Loperamide looks like and contents of the pack
Loperamide Hydrochloride 2 mg capsule is a hard gelatin capsule of size '4' filled with white to off white powder with grey cap and green body. Loperamide Hydrochloride 2mg capsule are available in blister packs containing 4 and 6 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:
 **NOUMED LIFE SCIENCES LIMITED**
Noumed House, Shoppenhangers Road,
Maidenhead, Berkshire, SL6 2RB, United Kingdom

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To listen to or request a copy of this leaflet in Braille, large print or audio please call, 020 33 99 8960 (UK only)
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