Loperamide Hydrochloride 2mg leaflet front

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Pharma Code

Package leaflet: Information for the patient

Loperamide Hydrochloride 2mg Capsules

- This medicine is used for two different types of diarrhoea. They have **different age limits.** *See Section 1*
- **Do not take this medicine:**
  - There are some **people who should not use** this medicine. *To find out if you are one of them, see Section 2*
  - If you have ever had a **bad reaction** to any of the ingredients. *For the list of ingredients, see Section 6*
- **Speak to your doctor:**
  - If you suffer from any of the conditions mentioned in *Section 2*
  - If you are taking any **other medicines.** *See Section 2*
- **If you have Irritable Bowel Syndrome (IBS)** *see also Section 2*. Extra warnings for IBS patients.
- **Follow the dosage instructions carefully.** *See Section 3.*

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

Now read this whole leaflet carefully before you use this medicine. Keep the leaflet: you might need it again.

1. What Loperamide Hydrochloride 2mg capsules is for

Loperamide Hydrochloride 2mg capsules are 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 Hydrochloride 2mg capsules

Warnings for everyone

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

Do not take this medicine...

- if you have ever had a **bad reaction** to any of the ingredients.
- 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.**

If any of these applies to you, **talk to a doctor or pharmacist and do not take Loperamide Hydrochloride 2mg capsules.**

Talk to your doctor first...

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

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

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.

Some of the ingredients 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.
- This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

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.**
- 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 Hydrochloride 2mg capsules.**

3. How to take this medicine

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.

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.
- Do not use more than the dose shown in the tables.
- The capsules are **not for long-term treatment**.

Short-term diarrhoea

Age	Dose
Adults and children aged 12 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**

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Item Code: XXXXXX

Pharma Code

Pharma Code: Dummy

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capsules in a 24-hour period.
- *Replace lost fluid by drinking more liquid than usual.*
- Not for children aged under 12.

How long to take Loperamide Hydrochloride 2mg capsules for short-term diarrhoea
You can use this medicine for up to 48 hours.
If your attack lasts longer than 48 hours, stop taking Loperamide Hydrochloride 2mg capsules 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 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**.

How long to take Loperamide Hydrochloride 2mg capsules for IBS diarrhoea
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 Hydrochloride 2mg capsules and **talk to your doctor**.

If anyone takes too much of this medicine
If you have taken too many Loperamide Hydrochloride 2mg 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 2mg 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 the medicine
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

Loperamide Hydrochloride 2mg capsules can have side effects, like all medicines, although these don't affect everyone and most are usually mild.

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 side 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 Hydrochloride 2mg capsules

Keep this medicine out of the sight and reach of children.
Store in the original package.
Do not store above 25ºC.
Do not use this medicine after the expiry date which is stated on the carton. 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 Hydrochloride 2mg capsules contains
The active substance is loperamide hydrochloride.
Each hard gelatin capsule contains
loperamide hydrochloride 2 mg

The other ingredients are:
Lactose Anhydrous, Maize starch, Polysorbate 80, Talc, Magnesium stearate, Silica colloidal anhydrous.

Capsule cap:
Gelatin, Sodium laurilsulfate, Iron Oxide Yellow, Indigo Carmine, Titanium dioxide.

Capsule body:
Gelatin, Sodium laurilsulfate, Erythrosine, Iron oxide black, Titanium dioxide.

Imprinting Ink:
Shellac, Propylene glycol, Iron oxide black, Potassium hydroxide , Purified Water.

What Loperamide Hydrochloride 2mg capsules look like and contents of the pack

Green/Grey colored size '4' hard gelatin capsules imprinted with "C" on the cap and '24' on the body, filled with white to off white powder.
Loperamide Hydrochloride 2mg capsules are supplied in clear PVC/Aluminium blister of 6 capsules. Pack size: 12 capsules.

Marketing Authorisation Holder and Manufacturer:
ipca
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United Kingdom

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