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Loperamide 2mg Capsules, Hard **(GSL)**

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PACKAGE LEAFLET : INFORMATION FOR THE USER
Loperamide 2mg Capsules, Hard
(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 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.
- 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*

What is in this leaflet:

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

1. WHAT LOPERAMIDE CAPSULE IS AND WHAT IT IS USED FOR

Loperamide capsule is used to treat two types of diarrhoea. The two types have different age limits.

i. **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.**

ii. **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 CAPSULES

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.

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.
- have **severe diarrhoea** after taking **antibiotics.**
- are having a flare-up of an **inflammatory bowel condition** like **ulcerative colitis.**
- are **constipated,** or your **stomach appears swollen** (especially in children with severe dehydration).
- have **acute dysentery,** the symptoms of which may include **blood in your stools** and a **high temperature.**
- If it is for a child aged **under 12** (or under 18 for an IBS patient).

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

Other medicines and Loperamide
Talk to your doctor first 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 an **intolerance to some sugars.**
- have severe **diarrhoea** as your body loses more fluid, sugars and salts than normal.
- 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, breast-feeding and fertility
- **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.

Warnings and precautions
- 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.**
- 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 2mg Capsules, Hard.

Loperamide contains:
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 medicinal product.

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.**

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

3. HOW TO TAKE LOPERAMIDE CAPSULES

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 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 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 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 f**or 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 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 Capsules and **talk to your doctor**.

If you take more Loperamide than you should
If you have taken too many Loperamide 2mg Capsules, Hard, 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 2mg Capsules, Hard 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.

4. POSSIBLE SIDE EFFECTS

Loperamide 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), 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).

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 CAPSULES

Keep this medicine out of the sight and reach of children.
Store below 25°C. Store in the original package.
Do not use this medicine after the date shown as the expiry date on the packaging.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Loperamide Capsules contains
The active ingredient in Loperamide Capsules is: Loperamide hydrochloride 2 mg per capsule. The other ingredients are lactose monohydrate, microcrystalline cellulose, maize starch, colloidal anhydrous silica, purified talc, magnesium stearate. The capsule is made up of gelatin, water, sodium lauryl sulfate, patent blue V (E131), quinoline yellow (E104), brilliant blue FCF (E133), iron oxide red (E172) and titanium dioxide (E171). The printing ink contains shellac (E904), propylene glycol (E1520), black iron oxide (E172) and potassium hydroxide (E525).

What Loperamide Capsules looks like and contents of the pack
Loperamide Capsules are Size '4' Hard gelatin capsule with Green cap imprinted with 'L' in black ink and grey body imprinted with '2mg' in black ink, containing white to off-white powder.

Loperamide Capsules are available in blister packs of 2, 4 and 6 capsules (not all pack sizes may be marketed).

Marketing Authorization Holder
Flamingo Pharma (UK) Ltd.
1st Floor, Kirkland House, 11-15 Peterborough Road, Harrow, Middlesex, HA1 2AX, United Kingdom.

Manufacturer:
Flamingo Pharma (UK) Limited,
The Bloc,
38 Springfield Way,
Anlaby, Hull,
HU10 6RJ, United Kingdom.

If you would like this leaflet in different format information or want to report any side effects, please contact marketing authorization holder listed above.

This leaflet was last revised in 04/2022.

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