

## **PACKAGE LEAFLET**

## Package leaflet: Information for the patient

### Loperamide Hydrochloride 2 mg Hard 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 2 days.

#### 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 an anti-diarrhoea medicine. It works by slowing down the speed at which food and stomach contents pass through the bowel. This allows your body more time to take up water from your stool and so reduce diarrhoea.

Loperamide can be used:

- For the treatment of sudden, short-lived (acute) diarrhoea in adults and children over 12 years of age
- For the treatment of diarrhoea associated with Irritable Bowel Syndrome (IBS), which has been diagnosed by a doctor, in adults aged 18 years and over.

You must talk to a doctor if you do not feel better or if you feel worse after 2 days.

#### 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)
- If you or your child are under the age of 12 (or under 18 for an IBS patient)
- If you have noticed blood in your stools and have high fever
- If you have a medical condition that causes you to suffer from constipation (reduced frequency of bowel movements) such as a blockage in your intestines, or where constipation may cause a problem
- If you know you suffer from an inflamed intestine or inflammatory bowel disease (ulcerative colitis, Crohn's disease)
- If you have been told by your doctor that your abdominal pain, inflammation or diarrhoea is caused by bacteria such as *Salmonella*, *Shigella* or *Campylobacter*
- If you have severe diarrhoea after taking antibiotics.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Loperamide:

- If you know you suffer from liver problems

- If you are dehydrated. Your doctor may also give you another medicine containing sugar and salts (known as oral rehydration therapy) to help your body replace the fluid and salts lost during diarrhoea

During treatment:

- If you develop a bloated tummy or become constipated, treatment should be stopped immediately. This may be more likely to happen if you have AIDS.
- If you have a fever or notice blood in your stool, stop taking this medicine and speak to your doctor

You should also stop taking this medicine and speak to your doctor if there is no improvement in your condition within 48 hours. Prolonged diarrhoea may be a symptom of a more serious illness and you should not take Loperamide for a long period of time unless your doctor has told you to do so after investigating the cause of your diarrhoea.

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.

Extra warnings for treatment of diarrhoea associated with IBS:

Only take Loperamide to treat acute episodes of diarrhoea associated with Irritable Bowel Syndrome if your doctor has previously diagnosed IBS.

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 2 mg Hard Capsules.

If any of the following now apply, do not use the product 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, 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, especially any of the following:

- quinidine (used to treat abnormal heart rhythms or malaria)
- ritonavir (used to treat HIV)
- itraconazole (used to treat fungal infections)
- gemfibrozil (helps reduce cholesterol and triglycerides (fatty acids) in the blood)
- ketoconazole (used to treat infections caused by a fungus or yeast)
- desmopressin (used to treat excessive urination)
- any medicine being taken for any condition affecting your stomach

### **Pregnancy or 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 any 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 are affected do not drive, cycle or use machines.

### **Loperamide 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.

## **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 need will depend on whether your diarrhoea is a sudden, short-lived attack (acute) or related to ongoing IBS.

Swallow the capsule whole (do not chew) with some liquid. It is important to drink more fluids than you normally would during treatment with Loperamide to replace the fluids and salts lost because of the diarrhoea.

The recommended dose is:

### **Acute / Short term Diarrhoea**

#### **Adults (including Elderly) and Children aged 12 years and over**

Two capsules initially then one capsule after every loose stool. The recommended dosage is three to four capsules a day. Do not take more than 6 capsules in one day (24 hours).

If there is no improvement within 48 hours of starting treatment, speak to your doctor. Further investigation of the cause of the diarrhoea may be required.

### **Diarrhoea associated with IBS**

#### **Adults**

Two capsules initially then one capsule after every loose stool, or as your doctor has advised. Do not take more than 6 capsules per day.

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 speak to your doctor.

#### **Patients with liver problems**

Your doctor will advise you.

#### **If you take more Loperamide than you should**

Contact your doctor or nearest hospital emergency department **immediately**. Take the container and any remaining capsules with you. Symptoms of overdose include constipation, sleepiness or slower breathing.

If you have taken too many Loperamide Hydrochloride 2 mg Hard 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 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 the next dose as soon as you remember unless it is almost time for your next dose. **Do not** take a double dose to make up for a forgotten dose.

#### **If you stop taking Loperamide**

You should take Loperamide for as long as the doctor tells you to.

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.

If any of the following happen, **stop taking** Loperamide and tell your doctor immediately or go to your nearest hospital emergency department:

**Rare** (may affect up to 1 in 1,000 people):

- A serious allergic reaction. Such reactions may appear in the form of anaphylaxis (a severe form of allergic reaction) with symptoms such as:
  - itchy rash
  - shortness of breath
  - swelling of the face, lips, mouth, tongue or throat (angioedema)
  - anaphylactic shock (sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing)
- Skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with dark ring around the edge) (erythema multiforme)
- A widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens Johnson Syndrome).
- A widespread rash with blisters and skin peeling on much of the body surface (toxic epidermal necrolysis).
- Loss of consciousness or reduced level of consciousness (passing out, feeling faint or less alert), uncoordinated movements
- Widening of the large intestine (megacolon), this widening can be rapid and the following symptoms could be noticed; abdominal pain/tenderness, fever and rapid heart rate
- A blockage in the intestine (ileus), which would cause a lack of bowel movement (constipation) or wind, with abdominal pain or bloating, feeling or being sick especially after meals, with excessive belching
- Inability to pass urine

**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.

The following side effects may be seen with Loperamide:

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

- Headache

- Constipation, feeling sick, wind

**Uncommon** (may affect up to 1 in 100 people):

- Feeling sleepy or drowsy
- Stomach pain, stomach discomfort, upper stomach pain, indigestion
- Being sick
- Dizziness
- Dry mouth
- Rash

**Rare** (may affect up to 1 in 1,000 people):

- Feeling bloated
- Feeling tired
- Itching
- Tense or tight muscles
- Narrowing of the pupils in your eye (miosis)

### **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 (website:

[www.mhra.gov.uk/yellowcard](http://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.

Do not use this medicine after the expiry date which is stated on the carton, label or 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 any 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 2 mg loperamide hydrochloride.

The other ingredients are:

In the capsule contents: lactose monohydrate (see section 2, “Loperamide contains lactose”), maize starch and magnesium stearate.

The capsule shell contains: Quinoline yellow (E104), Indigo carmine (E132), erythrosine (E127), titanium dioxide (E171), black iron oxide (E172) and gelatin

The printing ink contains: ammonium hydroxide, povidone, shellac, simeticone, sodium hydroxide and titanium dioxide (E171), Propylene glycol

### **What Loperamide looks like and contents of the pack**

Your medicine comes as a hard mauve and green capsule marked “LOPERA-MIDE 2”.

Loperamide is available in blister strips containing 4, 6, 8, 10 and 12 capsules and in plastic bottles containing 4, 6, 8, 10 and 12 capsules.  
Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

Mylan, Potters Bar, Herts, EN6 1TL  
United Kingdom

**Manufacturer**

Generics [UK] Limited, Station Close, Potters Bar, Herts, EN6 1TL, United Kingdom

Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

**This leaflet was last revised in 12/2022.**