

## 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.

#### **Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

#### **What is in this leaflet**

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

#### **1. What Loperamide Hydrochloride 2mg capsules is and what it is used 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 are allergic to loperamide hydrochloride or any of the other 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.

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.

#### **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 rhythm 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 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 the mother's 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.
- 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.

#### **Loperamide Hydrochloride 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.

#### **Sodium content**

- 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 Loperamide Hydrochloride 2mg capsules**

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 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 and young people 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**

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), uncoordinated movements.

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 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](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 Hydrochloride 2mg capsules**

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. 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, Ethanol, anhydrous, Isopropyl alcohol, Butanol, Propylene glycol, Ammonia solution concentrated, Iron oxide black, Potassium hydroxide .

### **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 10 and 14 capsules. Pack size: 28, 30, 50, 56, 84 and 100 capsules.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer:**

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