

## LoModine 2mg Capsules Loperamide Hydrochloride

Read all of this leaflet carefully because it contains important information for you.  
Keep this leaflet, you may need to read it again.  
Ask your pharmacist if you need more information or advice.

### 1. What the medicine is for

This medicine is used to treat **two different 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 the active substance Loperamide hydrochloride which helps reduce diarrhoea by slowing down an overactive bowel.

### 2. Before taking this medicine

#### 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 or any of the ingredients in this medicine
- If it is for a child **under 12** (or under 18 for an IBS patient)
- 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 the above applies to you talk to your doctor or pharmacist before taking this medicine.

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 LoModine.

#### Talk to your doctor first:

- If you suffer from liver disease
- If you have diarrhoea that lasts more than 48 hours
- If you have severe diarrhoea as your body loses more fluid, sugars and salts than normal
- If you have been told by your doctor that you have an intolerance to some sugars.

#### Extra warnings for IBS patients

**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 this medicine**.

#### Other medicines and LoModine

Talk to your doctor first if you are taking any other medicines including:

- Quinidine – used to treat heart conditions or malaria
- Ritonavir – used to treat HIV
- Desmopressin – used to treat bed wetting
- Itraconazole or ketoconazole – used to treat fungal infections
- Gemfibrozil – used to treat high cholesterol.

#### 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 alternative.

#### Driving and using machines

This medicine can make you feel dizzy, tired or sleepy. If you think you are affected do not drive or operate machinery.

#### 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 normal. **This is especially important for children and frail or older people.** Ask your pharmacist about **rehydration therapy** to replace lost salts.

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.

#### 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.

### 3. How to take this medicine

**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.

140 x 260 mm

Front Page

#### ARTWORK DETAIL LABEL

<b>Product</b>	<b>LoModine 2 mg Capsules</b>				
Buyer/Country	Strides Pharma UK Ltd.	Component	Pack Insert		
<b>Dimension</b>	<b>140 x 260 mm</b>	Pack	--		
<b>New Item Code</b>	<b>1048466</b>	Old Item Code	1048163		
Colour Shades	 Pantone Reflex Blue U	 Pantone Process Blue U	 Black	No. of Colours	3
Change Control No.	PC-TSG/2023/007 - Record Number: 372556			Artwork Version	9.0
Design/Style	Front & Back Printing. To be supplied in the unfolded size.				
Substrate	60 GSM Paper.				
Special Instructions	Printing clarity to be clear & sharp.				
Autocartonator Requirements	<b>Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.</b>				
<b>Caution to the printer:</b> Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. <b>DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.</b>					

If you have taken too many LoModine, 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 LoModine than adults. If a child takes too much or shows any of the above symptoms, call a doctor immediately.

The capsules are **not for long-term treatment**.

#### Short-term diarrhoea

Age	Dose
<b>Adults and children aged 12 and over</b>	Take <b>two capsules</b> to start treatment. Take <b>one capsule</b> after each loose bowel movement.
<ul style="list-style-type: none"> <li>Do not take more than <b>six capsules</b> in a 24-hour period.</li> <li>Do not take for attacks lasting <b>longer than 48 hours</b>.</li> <li>If your attack lasts <b>longer than 48 hours</b>, stop taking LoModine and <b>talk to your doctor</b>.</li> </ul>	

#### IBS diarrhoea

Age	Dose
<b>Adults aged 18 and over</b>	Take <b>two capsules</b> to start treatment. Take <b>one or two capsules</b> after each loose bowel movement depending on severity of symptoms.
<ul style="list-style-type: none"> <li>Do not take more than <b>six capsules</b> in a 24-hour period.</li> <li>You can take this medicine <b>for up to 2 weeks</b> for repeated attacks but do not take for any one attack lasting <b>longer than 48 hours</b>.</li> <li>If any attack lasts <b>longer than 48 hours</b>, stop taking LoModine and <b>talk to your doctor</b>.</li> </ul>	

#### If you forget to take this medicine

You should only take this medicine as you need it, following the dosage instructions 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 LoModine can have side effects although these don't affect everyone.

If you experience any of the following **STOP TAKING this medicine and get medical help at once**.

**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.

**Rare (may affect less than 1 in 1,000 but 1 or more in 10,000 people)**

- Allergic reactions including unexplained wheeziness, shortness of breath, passing out, skin rashes or swelling of the face and throat
- Skin rashes, which may be severe and include blistering or peeling skin

- A swollen stomach, severe constipation or difficulty passing water
- Severe stomach pain or bloating with a fast heart rate, low blood pressure, (dizziness on standing) and high fever
- Loss of consciousness or reduced level of consciousness (feeling faint or less alert), uncoordinated movements.
- Talk to a doctor as soon as possible if you experience any of the following:

**Common (may affect less than 1 in 10 people but more than 1 in 100 people)**

- Headache
- Feeling sick, constipation, wind

**Uncommon (may affect less than 1 in 100 people but less than 1 in 1,000 people)**

- Drowsiness
- Dry mouth
- Abdominal pain, indigestion or discomfort
- Skin rash
- Dizziness
- Being sick.

**Rare (may affect less than 1 in 1,000 but 1 or more in 10,000 people)**

- Miosis (narrowing of the pupils of the eye)
- Tiredness
- Itchiness or hives.

#### 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)

By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. Storing this medicine

Keep the product out of the sight and reach of children.

Do not store above 25°C. Store your medicine in its original container.

Do not use your medicine after the expiry date shown on the packaging.

#### 6. Further information

##### What's in this medicine

The active ingredient in LoModine Capsules is loperamide hydrochloride.

Other ingredients are: lactose monohydrate, maize starch, magnesium stearate, quinolone yellow oxide (E104), indigo carmine (E132), titanium dioxide (E171), gelatin, erythrosine (E127) and black iron oxide (E172).

##### What the medicine looks like

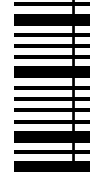
A white powder encapsulated within a size "4" hard gelatin capsules with a mauve opaque body and a dark green opaque cap printed "LOMODINE 2" [circular manner] on the cap in black.

They are available in packs of 4, 6, 8, 10 and 12 capsules. Not all pack sizes may be sold.

##### Marketing Authorisation Holder and Manufacturer

Strides Pharma UK Ltd.  
Unit 4, The Metro Centre  
Dwight Road, Watford  
WD18 9SS  
United Kingdom

**This leaflet was revised in February 2023.**



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PL 13606/0183






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