

# Loritax 2mg Capsules

## (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 doctor or pharmacist have 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 your doctor if you do not feel better or if you feel worse.

### What is in this leaflet

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

### 1. What Loritax is and what it is used for

Loritax contains the active substance loperamide hydrochloride which helps reduce diarrhoea by slowing down an overactive bowel.

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**

### 2. What you need to know before you take Loritax

#### Do not take Loritax

If you:

- are allergic to loperamide hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- are intending to give this medicine for a child **under 12** (or under 18 for an IBS patient)
- 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)
- have severe diarrhoea after taking antibiotics.

If any of the above applies to you talk to your doctor or pharmacist and do not take 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 hydrochloride, the active ingredient in Loritax.

#### Warning and precautions

Talk to your doctor or pharmacist before taking Loritax:

- 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
- If you have AIDS and your stomach becomes swollen, stop taking the capsules immediately and contact your doctor.

#### Extra warnings for IBS patients

**Use only if your doctor has previously diagnosed IBS.**

**Do not take this medicine if you are aged under 18.**

**Talk to your doctor or pharmacist before taking Loritax:**

- 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.**

#### Other medicines and Loritax

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes:

- 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 and 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 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 elderly 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.




#### Loritax 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.

140 x 280 mm

Front Page

#### ARTWORK DETAIL LABEL

<b>Product</b>	<b>Loritax 2 mg Capsules</b>			
Buyer/Country	Strides Pharma UK Ltd.	Component	Pack Insert	
Dimension	140 x 280 mm	Pack	--	
New Item Code	<b>1048464</b>	Old Item Code	1048161	
Colour Shades	 Pantone Reflex Blue U	 Pantone 536 U	 Black	
		No. of Colours	3	
Change Control No.	PC-TSG/2023/007 - Record No.: 372556		Artwork Version	8.0
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>				

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### 3. How to take Loritax

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

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
<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 Loritax and <b>talk to your doctor</b>.</li> <li><b>Not for children aged under 12 years.</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 capsule</b> after each loose bowel movement, or as previously advised by a doctor.
<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 Loritax and <b>talk to your doctor</b>.</li> <li><b>Not for children and young people aged under 18 years.</b></li> <li><b>Consult your doctor if you develop new symptoms, or if your symptoms worsen, or if your symptoms have not improved over 2 weeks.</b></li> </ul>	

#### Use in children and adolescents

Children react more strongly to large amounts of Loritax than adults. If a child takes too much or shows any of the below symptoms, call a doctor immediately.

#### If you take more Loritax than you should

If you have taken too many 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.

#### If you forget to take Loritax

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 to make up for a forgotten dose.

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 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 up to 1 in 1,000 people)

- Allergic reactions including unexplained wheeziness, shortness of breath, passing out, skin rashes or swelling of the face and throat
- Severe skin reactions which include blistering and peeling skin
- Loss of consciousness or reduced level of consciousness (feeling faint or less alert)
- 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.

Talk to a doctor as soon as possible if you experience any of the following:

#### Common (may affect up to 1 in 10 people)

- Headache
- Feeling sick, constipation, wind.

#### Uncommon (may affect up to 1 in 100 people)

- Drowsiness
- Dry mouth
- Abdominal pain, indigestion
- Skin rash
- Dizziness
- Vomiting (being sick).

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

- Tiredness (fatigue)
- Miosis (narrowing of the pupils of the eye).

#### 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 Loritax

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Store in the original package.

Do not use this medicine after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month.

### 6. Contents of the pack and other information

#### What Loritax contains

The active substance is loperamide hydrochloride.

The other ingredients are: lactose monohydrate (see section 2), maize starch, magnesium stearate, quinolone yellow oxide (E104), indigo carmine (E132), titanium dioxide (E171), gelatin, erythrosine (E127) and black iron oxide (E172).

#### What Loritax looks like and contents of the pack

A white powder encapsulated within a size "4" Hard Gelatin Capsules with a mauve opaque body and a dark green opaque cap.

They are available in packs of 2, 4 and 6 capsules. Not all pack sizes may be marketed.

#### 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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