

8805



PACKAGE LEAFLET: INFORMATION FOR THE USER

LOPERAMIDE HYDROCHLORIDE CAPSULES 2 mg

Loperamide Hydrochloride

Read all of this leaflet carefully before you start taking this medicine as 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 or nurse.
- This medicine has been prescribed for you only. 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. WHAT LOPERAMIDE HYDROCHLORIDE CAPSULES 2 mg IS AND WHAT IT IS USED FOR

Loperamide Hydrochloride is one of a group of medicines called "anti-diarrhoeals" which are used to treat diarrhoea.

Loperamide Hydrochloride is used to treat sudden, short-lived (acute) attacks of diarrhoea in adults and children 4 years and over and long-lasting (chronic) diarrhoea in adults. It works by making the stools more solid and less frequent.

REMEMBER - This medicine has been prescribed for you only. Do not give it to anyone else.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LOPERAMIDE HYDROCHLORIDE CAPSULES 2 mg

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.

Always inform your doctor if you are pregnant, think you might be pregnant or are trying to become pregnant.

Do not use Loperamide Hydrochloride Capsules:

- If you are allergic to Loperamide or any other ingredient in this product (listed in section 6)
- In children under the age of 4
- If your doctor has told you that you have a condition where slowing of the stomach or intestine should be avoided. For example: constipation, bloated tummy (particularly in children with severe dehydration or AIDS patients), inflammation of the bowel (eg. any form of colitis).

Loperamide Hydrochloride should not be used on its own in acute dysentery, the symptoms of which may include blood in your stools and a high temperature.

If in doubt about any of the above, ask your doctor or pharmacist.

Warnings and precaution

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 Capsules 2 mg**.

Talk to your doctor, pharmacist or nurse before taking this medicine:

- If you suffer from liver disease. You may need to be more

closely supervised during treatment and the dosage may have to be altered.

- If you have AIDs and notice signs of stomach distension (swelling) whilst taking Loperamide, stop taking them and see your doctor immediately.
- If your diarrhoea lasts for more than 2 days.

Loperamide Hydrochloride only treats the symptoms of diarrhoea. When you have diarrhoea, your body loses large amounts of fluid and salts. You should therefore replace this lost fluid by taking more liquids than you normally would. This is especially important for children.

Your doctor may have also given you a special powder containing sugar and salts (known as oral rehydration therapy) to help your body replace the fluid and salts lost during diarrhoea.

If you have been told by your doctor that you have an intolerance to some sugars, you should check with your doctor before taking this medicine.

Other medicines and Loperamide Hydrochloride Capsules 2mg
Always tell your doctor or pharmacist if you are unsure about taking any other medicines as you should not take any other anti-diarrhoeal preparations whilst taking Loperamide Hydrochloride (except for oral rehydration therapy - see under Warnings and precautions above).

Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription.

Especially:

- Quinidine used in heart conditions
- Ritonavir used in the treatment of HIV and AIDs
- Desmopressin used to treat bed-wetting.

Loperamide Hydrochloride Capsules 2 mg with food and drink
Swallow the correct number of capsules whole with some liquid.

Pregnancy

If you are pregnant, think you might be pregnant or are planning to become pregnant, you should talk to your doctor who will decide if you can take Loperamide Hydrochloride.

Breast-feeding

Do not take Loperamide Hydrochloride if you are breast-feeding as small amounts of the medicine may get into your milk. You should talk to your doctor about suitable treatment.

Driving and using machines

These capsules may cause dizziness, sleepiness or tiredness. If affected you should not drive or operate machinery or take part in activities where these may put you or others at risk.

Loperamide Hydrochloride Capsules 2mg contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, you should talk to your doctor before taking this medicine.

3. HOW TO TAKE LOPERAMIDE HYDROCHLORIDE CAPSULES 2 mg

Always read the label on your medicine and follow your doctor's instructions carefully. Ask your pharmacist if you are not sure about anything.

The dose of Loperamide Hydrochloride that you will need will depend on whether your diarrhoea is a sudden, short-lived attack (acute) or a long-lasting condition (chronic).

Acute diarrhoea

Adults: take two capsules to begin with and then 1 capsule after each episode of diarrhoea for up to 5 days. Never take more than 8 capsules in any 24 hour period.

Children aged 9-12 years: take one capsule 4 times daily until diarrhoea is controlled or for up to 5 days. Never take more than this dose.




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Front Side Printing

Size : 180 x 230mm

ARTWORK DETAIL LABEL

Product	Loperamide Hydrochloride Capsules 2 mg			
Buyer/Country	Strides Pharma UK Ltd.	Component	Pack Insert	
Dimension	180 x 230 mm	Pack	-----	
New Item Code	1040943	Old Item Code	1035078	
Colour Shades	 Black	No. of Colours	1	
Change Control No.	PC-ODF/2023/109 - Record Number: 377521		Artwork Version	8.0
Design/Style	Front & Back Printing. To be supplied in UNFOLDED size.			
Substrate	60 GSM Paper.			
Special Instructions	Printing clarity to be clear & sharp.			
Autocartonator Requirements	Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.			
Caution to the printer: 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. DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.				

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Children aged 4-8 years: Not recommended for use in children aged 4-8 years. Your doctor will prescribe a suitable alternative. If your symptoms are not getting better within 2 days of taking your first dose of Loperamide Hydrochloride, you should see your doctor again. The reason is that your doctor may want to examine you to further check on the cause of the diarrhoea.

Chronic diarrhoea
Adults only: your doctor will tell you how much Loperamide Hydrochloride to take. The initial dose will probably be between two and four capsules per day taken in divided doses, but will depend on each individual's needs. When your doctor is satisfied that you are receiving the daily dose that best suits you, he or she will probably suggest that the frequency at which you take Loperamide Hydrochloride is twice a day. Never take more than 8 capsules in any 24 hour period.

Children: NOT recommended.
If you take more Loperamide Hydrochloride Capsules 2 mg than you should
 If you have taken too many **Loperamide Hydrochloride Capsules 2 mg**, 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 Capsules 2 mg**, 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 Hydrochloride Capsules 2 mg
 If you forget to take a dose, take it as soon as you remember, unless it is nearly time for your next dose. Never take two doses to make up for forgotten doses. If you are worried ask your pharmacist or doctor for advice.

4. POSSIBLE SIDE EFFECTS
 Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious Side effects:
 Allergic reactions to Loperamide Hydrochloride are very rare (less than 1 in 10,000 patients affected). An allergic reaction can be recognised, by skin rash, itching, shortness of breath or swollen face. **If any of these signs occur, stop taking Loperamide Hydrochloride and see your doctor immediately.**

Severe bloated tummy or stoppage of bowel activity or difficulty urinating (passing water) have been reported. **If this should occur, stop taking Loperamide Hydrochloride and contact your doctor.**

If you have severe stomach pain or bloating, with a swollen abdomen, fast heart beat, low blood pressure (dizziness on standing) and high fever **stop taking Loperamide Hydrochloride and contact your doctor immediately.**

If you experience loss of consciousness or a reduced level of consciousness, or uncoordinated movements **stop taking Loperamide Hydrochloride and contact your doctor immediately.**

If you experience very painful skin blistering that may peel **stop taking Loperamide** and **contact your doctor or hospital immediately** as this may be a very serious skin disorder.

Common side effects (affects less than 1 in 10 patients)

- Headache
- Constipation
- Nausea
- Flatulence (wind).

Uncommon side effects (affects less than 1 in 100 patients)

- Dizziness
- Drowsiness
- Stomach pain and discomfort (including cramps)
- Vomiting
- Indigestion
- Skin rash
- Dry mouth.

Rare side effects (affects less than 1 in 1000 patients)

- Eye problems such as constriction of the pupils
- Tiredness
- Itching and hives.

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

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

5. HOW TO STORE LOPERAMIDE HYDROCHLORIDE CAPSULES 2 mg
 As with all medicines, Loperamide Hydrochloride should be kept in a safe place where children cannot see or reach it. Do not store above 25°C. Store the medicine in its original container.
 Do not use the medicine after the expiry date printed on the packaging. Always return any left over medicine to your pharmacist. Only keep it if your doctor tells you to.

6. CONTENTS OF THE PACK AND OTHER INFORMATION
What Loperamide Hydrochloride Capsules 2 mg contains
 The active substance(s) is Loperamide Hydrochloride.

What Loperamide Hydrochloride Capsules 2 mg looks like and contents of the pack
 Hard gelatin capsules. A white powder encapsulated within a Size "4" Hard Gelatin Capsules with a mauve opaque body and a dark green opaque cap, printed "Loperamide 2" [Circular manner] on the cap in black. Contents of pack: 10 capsules packed in a blister and 3 such blisters packed in a carton.

Marketing Authorisation Holder and Manufacturer
 Strides Pharma UK Ltd.
 Unit 4, The Metro Centre
 Dwight Road, Watford,
 WD18 9SS
 United Kingdom

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Back Side Printing



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