

Loperamide 2 mg Capsules

Package leaflet: Information for the user

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 a doctor if you do not feel better or if you feel worse after 48 hours.

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 belongs to a group of drugs called anti-diarrhoeals. It 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.

Loperamide is used:

- to treat the symptoms of short-lived (acute) cases of diarrhoea in adults and children aged 12 years and over
- to treat acute diarrhoea associated with Irritable Bowel Syndrome in adults following diagnosis by a doctor.

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 have acute dysentery, which is characterised by blood in your stools and a high temperature
- if you are having a flare up of an inflammatory bowel condition, such as ulcerative colitis
- if you have severe diarrhoea after taking antibiotics
- if you have constipation, or any form of blockage of the bowel
- if you have a swollen stomach.

these capsules should not be taken by children under 12 years old.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine:

- if you have liver problems
- if you have **AIDS**.

Extra warnings for IBS patients

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

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.

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.

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 2 mg Capsules.

Other medicines and Loperamide

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine:

- quinidine (used to treat an uneven heart beat)
- ritonavir (used to treat HIV)
- itraconazole or ketoconazole (used to treat fungal infections)
- gemfibrozil (used to reduce high fat levels (cholesterol and triglycerides) in the blood)
- desmopressin (reduces the amount of urine produced by the kidneys)

Pregnancy, breast-feeding and fertility

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 treatment.

Driving and using machines

Loperamide may make you feel tired, dizzy or drowsy. You may feel less alert, feel faint or pass out. Do not drive or use machinery until you are sure you are not affected.

Important information about some of the ingredients of Loperamide

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

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.

When you have diarrhoea, your body loses large amounts of fluid and salts which need to be replaced. This is particularly important for children and frail or elderly patients. You need to replace the fluid by drinking more liquid than usual. You can replace the lost salts by taking oral rehydration therapy. Ask your pharmacist for advice about these.

The capsules should be swallowed preferably with a drink of water.

Acute Diarrhoea

• Adults (including the elderly)

Two capsules should be taken to start with, followed by a further capsule after each episode of diarrhoea. Do not take more than 6 capsules a day.

• Children 12-17 years

One capsule should be taken to start with, followed by a further capsule after each

episode of diarrhoea. Do not take more than 3 capsules per 20 kg of the child's bodyweight, up to a maximum of 6 capsules a day. If you still have diarrhoea after 48 hours treatment, you should consult your doctor.

Irritable Bowel Syndrome

• Adults (including the elderly)

Two capsules should be taken to start with. The usual dose is 2 to 4 capsules a day in divided doses. Do not take more than 6 capsules a day.

If the pattern of your symptoms changes you should return to your doctor. You should also return to your doctor if your episodes of acute symptoms continue for more than two weeks or if you require treatment for more than two weeks.

Children under 12 years

Loperamide is not recommended for use in children under 12 years.

If you take more Loperamide than you should

If you have taken too many Loperamide 2 mg 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, constipation or weak breathing.

Children react more strongly to large amounts of Loperamide 2 mg Capsules than adults. If a child takes too much or shows any of the above symptoms, call a doctor immediately.

Please take this leaflet, any remaining capsules and the container with you to the hospital or doctor so that they know which capsules were consumed.

If you forget to take Loperamide

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 to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 Possible side effects

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

If the following happens, **stop taking the capsules and tell your doctor immediately** or go to the casualty department at your nearest hospital:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives)
- blisters/bleeding/peeling of the lips, eyes, nose, mouth and genitals
- loss of consciousness or reduced level of consciousness (passing out), feeling faint or less alert, uncoordinated movements.

These are very serious but rare side effects. You may need urgent medical attention or hospitalisation.

- **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.

Talk to a doctor as soon as possible

Uncommon (may affect up to 1 in 100 people)

- itchiness or hive
- 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 taking the capsules and **talk to a doctor**.

Other side effects that may occur

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

- constipation, feeling sick (nausea), wind (flatulence)
- 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 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 at: 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. These capsules should be stored in the package or container supplied. Do not transfer them to another container.

Do not use Loperamide after the expiry date which is stated on the outer packaging. 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 protect the environment.

6 Contents of the pack and other information

What Loperamide capsules contain:

- The active ingredient is loperamide hydrochloride.
- The other ingredients are maize starch, lactose monohydrate, povidone (E1201), sodium starch glycolate (Type A) and magnesium stearate (E572). The capsule shell contains gelatin, titanium dioxide (E171), yellow iron oxide (E172) and patent blue V (E131). The printing ink contains shellac, simeticone, titanium dioxide (E171) and propylene glycol (E1520).

What Loperamide capsules look like and contents of the pack:

- The Loperamide capsules are green and dark grey capsules containing a fine white powder. They are printed 'LOP2'.
 - The product is available in pack sizes of 10 and 12 capsules.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom.

Manufacturer

TEVA Pharmaceutical Works Private Limited Company, Pallagi street 13, Debrecen, H-4042, Hungary.

This leaflet was last revised in April 2022.

PL 00289/1979



13371_s1