

Package leaflet: Information for the user

Loperamid Brown 2 mg Capsules, hard (loperamide hydrochloride)

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 or nurse.
- This medicine has prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What <Product Name> is and what it is used for

<Product Name> is used:

- To treat sudden short-lived (acute) attacks of diarrhoea in adults and children aged 12 years and above.
- To treat long-lasting (chronic) diarrhoea in adults

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 <Product Name>

Do not take <Product Name>

- If you are allergic to loperamide hydrochloride, or any of other ingredients of this medicine (listed in section 6).
 - a. If it is for a child aged under 12.
 - b. If you have severe diarrhoea after taking antibiotics.
 - c. If you are having a flare-up of an inflammatory bowel condition like ulcerative colitis or pseudomembranous colitis caused by antibiotics.
 - d. If you are constipated, or your stomach appears swollen (especially in children with severe dehydration).

- e. If you have acute dysentery, the symptoms of which may include blood in your stools and a high temperature (intestinal infection caused by bacteria such as Salmonella, Shigella and Campylobacter)

If any of these applies to you, talk to a doctor or pharmacist and do not take Loperamide

Warnings and precautions

Talk to your doctor or pharmacist before taking <Product Name>

- If you have AIDS and your stomach becomes swollen, stop taking <Product Name> immediately and contact your doctor.
- If you suffer from liver disease.
- 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 temporary diarrhea does not stop after two days of treatment, stop treatment and consult a doctor.
- In case of signs of constipation or other signs of impaired intestinal passage, discontinue treatment and consult a doctor.

Other medicines and <Product Name>

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

- ritonavir (used to treat **HIV**).
- quinidine (used to treat **abnormal heart rhythms or malaria**).
- oral desmopressin (used to control thirst and treat **excessive urination** in patients with diabetes insipidus and bedwetting in children and nocturnal urge to urinate in adults).
- itraconazole or ketoconazole (used to treat **fungal infections**).
- cholestyramine and gemfibrozil (used to treat **high cholesterol**).
- ciclosporin (suppresses the immune system).
- verapamil (blood pressure lowering).
- erythromycin and clarithromycin (antibiotics).

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, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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 <Product Name>.

<Product Name> contains lactose

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

<Product Name> contains carmoisine and sunset yellow FCF which may cause allergic reactions

3. How to take <Product Name>

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.
- <Product Name> is 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 <Product Name> for attacks lasting **longer than 48 hours**.
- Do not take more than **eight 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 <Product Name> for short-term diarrhoea

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**.

Long-lasting (chronic) diarrhoea

Adults

- Your doctor will tell you how many <Product Name> capsules to take. This will depend on how serious your condition is
- You will probably start with a dose of between 2 and 4 capsules spread out over a day
- Your doctor will find the dose that suits you best. He or she may then suggest you take the capsules twice a day

- Never take more than eight capsules in any 24 hour period

If you take more <Product Name> than you should

If you take more Loperamide 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 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 <Product Name>

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.

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)

- Swelling of the face, tongue or throat, difficulty swallowing or hives and difficulty breathing. These are signs of angioedema. Loss of consciousness or reduced level of consciousness (passing out, feeling faint or less alert), extreme tiredness, uncoordinated movements.
- severe stomach pains and/or swollen stomach which may be signs of blocked or enlarged bowel.
- Lyell's syndrome (toxic epidermal necrolysis): Severe widespread skin damage (skin peeling of the epidermis and superficial mucous membranes).
- Stevens-Johnson syndrome: An extremely strong allergic reaction with a skin rash usually in the form of blisters or sores in oral cavity and eyes and other mucous membranes, for example genitalia.

Not known: (frequency cannot be estimated from the available data)

Upper abdominal pain, abdominal pain that radiates to back, tenderness when touching the abdomen, sore stomach, fever, rapid pulse, nausea, vomiting, which may be symptoms of inflammation of the pancreas (acute pancreatitis).

If you get any of these, **stop using <Product Name> 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 effects that may occur

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

- constipation, nausea or wind.
- Headache and dizziness.

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

- Dizziness or drowsiness.
- Vomiting, indigestion.
- Dry mouth.
- Pain or discomfort in the stomach.
- Rash.

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

Hypersensitivity reactions such as anaphylactic shock, muscle tension, small pupils, itching, hives and difficulties to pee

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 [to be completed nationally].

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

5. How to store <Product Name>

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

Store below 25°C.

Do not use this medicine after expiry date which is stated on the label, carton or bottle after EXP. The expiry refers to last day of the month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What <Product Name> contain

The active ingredient in <Product Name> is: loperamide hydrochloride 2 mg per capsule.

Other ingredients are: Lactose monohydrate, pregelatinized maize starch, talc and magnesium stearate.

Capsule shell: Carmoisine (E122), patent blue V (E131), quinoline yellow (E104), sunset yellow FCF (E110), titanium dioxide (E171), gelatin, iron oxide black (E172), iron oxide red (E 172), iron oxide yellow (E 172)

What <Product Name> look like and contents of the pack

<Product Name> are green opaque cap, grey opaque body, size '4', hard gelatin capsules, filled with white to off white powder. Approximately 14 mm in length.

They are available in blister packs (Alu-PVC/Aclar, Alu-Clear PVC) of 6, 10, 12, 18, 30, 40, 60 and 100's capsules & HDPE bottle pack of 250 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

This leaflet was last revised in 2024-12-19