

Package leaflet: Information for the user

Lopacut 2 mg film-coated tablets 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, pharmacist or nurse has 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, pharmacist or nurse. 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 you feel worse after 2 days.

What is in this leaflet

1. What Lopacut is and what it is used for
2. What you need to know before you take Lopacut
3. How to take Lopacut
4. Possible side effects
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1. What Lopacut is and what it is used for

Lopacut contains loperamide hydrochloride. It belongs to the group of medicines known as antidiarrhoeals.

Lopacut is used:

- to relieve the symptoms of sudden, short-term diarrhoea (acute diarrhoea) in adults and adolescents over 12 years.

Lopacut works by making the stools (motions) more solid and less frequent.

Doctor may prescribe this medicine for other purposes too.

You must talk to a doctor if you do not feel better or if you feel worse after 2 days.

2. What you need to know before you take Lopacut

Do not take Lopacut

- if you are allergic to loperamide or any of the other ingredients of this medicine (listed in section 6).
- if your stool includes blood or you have diarrhoea with high fever.
- if you have inflammation in the large intestine (*colitis ulcerosa* or *pseudomembranous colitis* after taking antibiotics).
- if you have enterocolitis caused by invasive organism such as *Salmonella*, *Shigella* and *Cambylobacter*.
- if the passage of food through the gut is already slow, *eg.* if you have constipation or suffer from swelling of the abdomen.
- if you have long-term diarrhoea (chronic diarrhoea).

Warnings and precautions

- The use of Lopacut may mask the symptoms of sudden worsening of long-lasting inflammation in the stomach and intestines (chronic inflammatory bowel diseases).
- Treatment with Lopacut relieves symptoms but does not cure the cause. Therefore, the underlying disease should be investigated and treated in the first place before long-term therapy.
- If sudden diarrhea is not stopped after two days of treatment, stop treatment and take contact to a doctor.
- If the signs of constipation or other signs of impaired bowel movement occur, stop treatment and take contact to a doctor.
- If you have impaired liver function, you should consult a doctor before treatment begins with Lopacut.
- At the diarrhea condition, you lose a lot of fluid. It is therefore important that you replace fluid loss by drinking a lot.
- If you have AIDS, you should discontinue treatment with Lopacut at the first sign of swollen stomach.
- 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 heart beat) have been reported in patients who have taken too much loperamide, the active ingredient in Lopacut.

Children

Lopacut is not intended for children under age of 12 years.

Other medicines and Lopacut

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

Certain drugs may affect the Lopacut treatment or Lopacut can affect certain drugs, if used simultaneously. Examples of such medicinal agents are:

- cholestyramine (lowers serum cholesterol levels) may decrease Lopacut absorption.
- quinidine (corrects heart rhythm)
- verapamil (lowers blood pressure)
- ritonavir (against HIV/AIDS)
- cyclosporin (an immunosuppressant drug)
- erythromycin and clarithromycin (antibiotics)
- itraconazole and ketoconazole (antifungal drugs)
- desmopressin (used to treat diabetes insipidus and bed-wetting)
- anticholinergics (used to treat Parkinson's disease and asthma) may strengthen the effect of Lopacut by slowing stomach and bowels emptying.

Consult a doctor before using Lopacut if you use any of the above mentioned medicine.

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

There is no sufficient data about the use of loperamide during pregnancy, therefore you should consult your doctor before using Lopacut if you are pregnant.

Loperamide passes into the breast-milk, therefore it is not recommended to be used during breast-feeding. Consult your doctor before using Lopacut during breast-feeding.

Driving and using machines

Tiredness, dizziness and drowsiness may occur during treatment with Lopacut.

You are responsible for assessing whether you are in fit condition to drive or perform tasks that demand increased attention. One of the factors that may affect your ability to do these is the effects and/or side effects of used drugs. Description of these effects and side effects can be found in other sections. Read all the information in this leaflet for guidance. If you experience effects affecting your attention, you should not drive or use any machines. Discuss with your doctor or pharmacist if you are unsure.

3. How to take Lopacut

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.

Use in adults and adolescents over 12 years of age

2 tablets initially, followed by 1 tablet after every loose stool, not earlier than 2-3 hours after the initial dose. The maximum daily dose should not exceed 6 tablets for adults (12 mg maximum daily dose) and 4 tablets for adolescents (8 mg maximum daily dose). You should not use Lopacut longer than 2 days without consultation of a doctor.

If you take more Lopacut than you should

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

If you forget to take Lopacut

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.

Stop using Lopacut and tell your doctor immediately if you experience the following symptoms:

- swollen face, lips, tongue or throat, difficulty to swallow and to breath (angioedema) and/or hives (also known as nettle rash or urticaria)
- severe irritation, reddening or blistering of your skin, mouth, eyes and genitals (bullous eruptions, **including Stevens-Johnson syndrome, erythema multiforme and toxic epidermal necrolysis**).
- 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).

The following review covers side effects reported to date in terms of their frequency.

Common (may affect up to 1 in 10 people)

- constipation
- flatulence
- abdominal cramping and colic
- nausea
- dizziness
- headache

Uncommon (may affect up to 1 in 100 people)

- somnolence
- dryness of mouth
- abdominal pain
- abdominal discomfort
- abdominal pain upper
- vomiting
- indigestion (dyspepsia)
- rash

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

- loss of consciousness
- lack of critical cognitive function and level of consciousness (stupor)
- decreased level of consciousness
- abnormal increase in muscle tension (hypertonia)
- coordination abnormality
- constriction of the pupil of the eye (miosis)
- difficulties in urinating (urinary retention)
- blockage in the intestines (ileus)
- bloating (abdominal distension)
- enlarged colon (megacolon including toxic megacolon)
- allergic (hypersensitivity) reactions
- nettle rash (urticaria)
- itching of the skin (pruritus)
- rapid swelling of face, lips, tongue or throat (angioedema)
- severe skin and mucosal changes (bullous eruptions)
- fatigue

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

- drowsiness
- acute pancreatitis

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 national reporting system listed in Appendix V*](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lopacut

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

This medicinal product does not require any special storage conditions.

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

Do not use this medicine if you notice the tablets are damaged or don't look right in some other way.

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 Lopacut contains

The active substance is loperamide hydrochloride, 2 mg in one tablet.

The other ingredients are:

Tablet core: microcrystalline cellulose, pregelatinized starch, croscarmellose sodium, colloidal anhydrous silica and magnesium stearate.

Tablet coating: polydextrose, hypromellose, titanium dioxide (E 171) and macrogol.

What Lopacut looks like and contents of the packAppearance:

Tablets are white, round and convex with logo “6”. Diameter is 8 mm.

Pack sizes:

8 and 10 film-coated tablets in blister (PVC/Al).

Marketing Authorisation Holder and Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:

Lopacut (CZ, DE, DK, EE, FI, HU, LT, LV, NO, PL, SE, SI, SK)

This leaflet was last revised in 2022-06-01