Package leaflet: Information for the user

Loperamide Grindeks 2 mg hard capsules
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.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Loperamide Grindeks is and what it is used for

Loperamide Grindeks hard capsules contain the active substance loperamide hydrochloride.
Loperamide hydrochloride makes stool harder and reduces the frequency and volume of bowel movements.

Loperamide Grindeks is used for the symptomatic treatment of sudden short-lasting (acute) attacks of diarrhoea in adults and adolescents over 12 years of age.

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

2. What you need to know before you take Loperamide Grindeks

Do not take Loperamide Grindeks hard capsules
- if you are allergic to loperamide hydrochloride or any of the other ingredients of this medicine (listed in section 6);
- below the age of 2 years;
- if you have blood in your stools or high fever;
- if you have acute ulcerative colitis;
- if you suffer from certain intestinal inflammations of bacterial origin *(Salmonella, Shigella, Campylobacter)*;
- if you have pseudomembranous (antibiotic-induced) intestinal inflammation;
- if you have constipation, bloated stomach or intestinal obstruction.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist.

Warnings and precautions
Talk to your doctor or pharmacist before taking Loperamide Grindeks hard capsules.
- Treatment with Loperamide Grindeks is only symptomatic, but does not resolve the underlying cause. Whenever possible, causal therapy should be aimed in all cases.

- Diarrhoea is associated with fluid and salt loss therefore special care should be taken to replace them, especially in children, and frail or older people. Drink more liquid than usual to replace the fluid and ask your doctor or pharmacist about rehydration therapy to replace lost salts.
- In infectious diarrhoea Loperamide Grindeks does not replace antibacterial treatment.
- In case of sudden acute diarrhoea Loperamide Grindeks hard capsules usually resolve the symptoms within 48 hours. If not, stop taking the medicine and see a doctor.
- Do not take Loperamide Grindeks hard capsules if your doctor advised you to avoid treatments that slow down your bowel movements. This may be the case, for example, if you have constipation or bloating.
- In case of signs of bloating when treating diarrhoea in AIDS patients, taking Loperamide Grindeks hard capsules should be stopped and consulting a doctor is advised.
- Tell your doctor if you have liver problems, as this may require closer medical supervision while you are taking Loperamide Grindeks hard capsules.

Use this medicine only for the specified indication (see Section 1) and never take more than the recommended dose (see Section 3). Serious heart problems (symptoms include fast or irregular heartbeat) have been reported in patients who took too much loperamide, the active substance of Loperamide Grindeks hard capsules.

Other medicines and Loperamide Grindeks hard capsules
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Medicines that accelerate gastrointestinal function may reduce the effect of Loperamide Grindeks.
The effect of desmopressin may be increased when Loperamide Grindeks are taken with oral desmopressin (a medicine used to treat a condition called central diabetes insipidus).

The following active substances may increase the level of loperamide hydrochloride in your blood:
- quinidine (used to treat and prevent heart rhythm problems)
- ritonavir and saquinavir (a medicine used to treat immunodeficiency)
- itraconazole, ketoconazole (used to treat fungal infections of the skin)
- gemfibrozil (used to lower blood lipids)
- st. John's wort (used to improve mood and treat mild depression)
- valerian (used to treat mild states of nervousness and anxiety)
- opioid analgesics (used to treat very severe pain) as this may increase the risk of severe constipation and central nervous system depression (for example drowsiness or decreased consciousness).

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.

<u>Pregnancy</u>
The use of Loperamide Grindeks should be avoided during pregnancy, especially during the first trimester of pregnancy. In case of known or suspected pregnancy ask your doctor for advice who will decide if you can take Loperamide Grindeks.

Breast-feeding
Small amounts may get into breast milk. Talk to your doctor about a suitable treatment.

Driving and using machines
If you feel tired, drowsy or dizzy while taking Loperamide Grindeks hard capsules (or due to diarrhoea), you should not drive or use machines.

Loperamide Grindeks contains lactose
Each capsule of Loperamide Grindeks contains 95 mg 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.

3. How to take Loperamide Grindeks

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Recommended dose

Adults
The initial dose is 2 capsules (4 mg) followed by 1 capsule (2 mg) after each subsequent loose stool.
The total daily dose should not exceed 6 capsules (12 mg).

Adolescents over 12 years of age
The initial dose is 2 capsules (4 mg) followed by 1 capsule (2 mg) after each subsequent loose stool.
The total daily dose should not exceed 4 capsules (8 mg).

Children below 12 years of age
Other medicines containing loperamide may be more appropriate for children aged 2 to 12 years.
Use in children aged 2-12 years cannot be made without medical prescription.
Loperamide must not be given to children below 2 years of age.

Elderly
No dose adjustment is required for the elderly.

Renal impairment
No dose adjustment is required for patients with renal impairment.

Hepatic impairment
Medicines containing loperamide hydrochloride should be used with caution in patients with hepatic impairment. If you suffer from hepatic impairment talk to your doctor before taking Loperamide Grindeks hard capsules.

Method of administration
The capsules should be swallowed in a whole, with some liquid. The capsules should not be chewed because of bitter taste. The capsules can be taken any time during the day with or without food.

Duration of treatment
You should stop taking the medicine and talk to your doctor if the symptoms do not resolve within 48 hours.

The maximum duration of treatment is 48 hours.

If you take more Loperamide Grindeks than you should
If you take too many Loperamide Grindeks hard capsules talk to a doctor or go to a hospital straight away for advice. Symptoms may include: increased heart rate, irregular heartbeat, changes in heartbeat (these symptoms can have potentially serious, life-threatening consequences), intestinal obstruction, constriction of the pupils (myosis), reduced sensibility and response to stimuli (stupor), muscle stiffness, uncoordinated movements, drowsiness, dry mouth, abdominal discomfort, nausea, vomiting, constipation, difficulties of passing urine and shortness of breath.

Children respond more expressively to larger amounts of loperamide hydrochloride than adults. If a child has taken too much of the medicine or shows any of the above symptoms call a doctor immediately.

If you forget to take Loperamide Grindeks
Do not take a double dose to make up for a forgotten capsule.

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.

Treatment with loperamide hydrochloride is generally well tolerated however side effects such as constipation and bloating or difficulties of passing urine may still occur even if the instructions are followed.

Constipation, more severe abdominal bloating and blockage of the bowel (ileus) may occur with the use of loperamide hydrochloride. If you notice any of the above stop taking Loperamide Grindeks hard capsules immediately and contact a doctor.

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) may occur. The frequency is not known (frequency cannot be estimated from the available data).
If you get any of these, stop taking the medicine and get medical help at once.

Isolated cases of hypersensitivity reactions (angioedema) with swelling of the face, tongue and throat, more severe skin symptoms and diseases have also been reported with loperamide hydrochloride:
- Severe skin disease with rash, peeling of the skin and mucosal ulcers (Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Acute inflammatory skin disease associated by blistering of the mucous membranes of the mouth and lips (erythema multiforme).

If you notice any of the above stop taking Loperamide Grindeks immediately and contact a doctor.

Adverse reactions reported in clinical trials and post-marketing

<u>Common adverse reactions</u> (may affect up to 1 in 10 patients)
- headache, dizziness
- constipation, nausea, increased flatulence.

<u>Uncommon adverse reactions</u> (may affect up to 1 in 100 patients)
- drowsiness
- abdominal pain, abdominal discomfort, dry mouth, vomiting, indigestion
- rash.

<u>Rare adverse reactions</u> (may affect up to 1 in 1000 patients)
- hypersensitivity reaction, anaphylactic reaction (including anaphylactic shock), anaphylactoid reaction, angioedema

- loss of consciousness, reduced sensibility and response to stimuli (stupor), reduced level of consciousness, increased muscle tone, coordination difficulties
- constriction of the pupils
- abdominal distension
- blockage of the bowel (ileus), disease of the colon (megacolon, including toxic megacolon)
- painful tongue
- hives, itchiness
- difficulties of passing urine
- tiredness.

Several symptoms may occur during treatment with Loperamide Grindeks that are usually difficult to distinguish from the symptoms associated with diarrhoea, such as nausea, abdominal pain, vomiting, tiredness, dizziness, drowsiness, dry mouth, flatulence, loss of appetite.

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 national reporting system: HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Loperamide Grindeks

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

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

This product does not require any special storage conditions.

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 Grindeks hard capsule contains
- The active substance is loperamide hydrochloride. Each hard capsule contains 2 mg loperamide hydrochloride.
- The other ingredients are: lactose monohydrate, maize starch, magnesium stearate (E572). *Capsule shells:* gelatin (E441), titanium dioxide (E171), iron oxide red (E172), iron oxide yellow (E172), brilliant blue FCF (E133).

What Loperamide Grindeks hard capsule looks like and contents of the pack
Hard gelatin capsules No. 3 (approximately 16 mm × 6 mm) with pink body and dark-green cap, the content - white powder. Pack sizes: 6, 8, 10, 12, 18 or 20 capsules in PVC/Alu blisters are packed in a cardboard box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and manufacturer
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This medicine is authorised in the Member States of the European Economic Area under the following names:

Hungary	Loperamide Grindeks 2 mg kemény kapszula
Austria	Loperamid Grindeks 2 mg Hartkapseln
Belgium	Loperamide Grindeks 2 mg harde capsules
Bulgaria	Loperamide Grindeks 2 mg hard capsules Лоперамид Гриндекс 2 mg твърди капсули
Czechia	Loperamide Grindeks
Germany	Loperamid Grindeks 2 mg Hartkapseln
Finland	Loperamide Grindeks 2 mg kapselit, kovat
France	LOPERAMIDE GRINDEKS 2 mg, gélule
Greece	Loperamide Grindeks 2 mg Σκληρά καψάκια
Croatia	Loperamidklorid Grindeks 2 mg tvrde kapsule
Ireland	Loperamide Grindeks 2 mg hard capsules
Italy	Loperamide Grindeks
The Netherlands	Loperamide Grindeks 2 mg harde capsules
Poland	Loperamide Grindeks
Portugal	Loperamide Grindeks 2 mg cápsulas duras
Romania	Loperamidă Grindeks 2 mg capsule
Slovakia	Loperamid Grindeks 2 mg tvrdé kapsuly
Spain	Loperamide Grindeks 2 mg cápsulas duras
Sweden	Loperamide Grindeks 2 mg hårda kapslar

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