

Patient Leaflet According to the Pharmacists' Regulations (Preparations) – 1986

This medicine is sold without a doctor's prescription

This medicine requires a doctor's prescription for children aged 6-12

Lopamide Capsules

Active ingredient:

Each capsule contains: Loperamide hydrochloride 2 mg

For the list of the other ingredients, see section 6. See also 'Important information about some of the medicine's ingredients' in Section 2.

Read this entire leaflet carefully before using the medicine.

This leaflet contains concise information about the medicine. If you have any further questions, please refer to your doctor or pharmacist.

This medicine is not intended for children and infants under the age of 6. Use it in the correct manner.

Consult your pharmacist if you require additional information. Refer to a doctor if the signs of the disease (symptoms) worsen or do not improve within 48 hours.

1. What is the medicine intended for?

The medicine is intended for the control and symptomatic relief of acute diarrhea.

Therapeutic group: slows down the intestinal (bowel) movements (antipropulsive).

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine (appear in section 6).
- Do not use this medicine in children under 6 years of age.
- You have high fever or bloody stools (signs of acute dysentery).
- You suffer from an inflammation in the intestines such as ulcerative inflammation (ulcerative colitis).
- You suffer from constipation or swelling in the abdominal region (especially in children with severe dehydration).
- You have diarrhea caused by antibiotic treatment.
- You have an intestinal infection caused by a bacterium such as Salmonella, Shigella or Campylobacter.
- You are taking medicines that reduce bowel movements.

Special warnings regarding the use of this medicine

• Before the treatment with this medicine, tell the doctor if:

- You suffer from a liver disease.
 - You are suffering from diarrhea that lasts for more than 48 hours.
 - You have been told that you have an intolerance to certain sugars.
 - You have severe diarrhea, since your body loses fluid, sugars and salts more than usual.
 - If you are pregnant, consult your doctor before taking Lopamide.
 - Do not take this medicine during the breastfeeding period.
- Lopamide treats diarrhea, but not the underlying cause of your condition. When you have diarrhea, your body loses large amounts of fluids and salts. To restore normal levels, it is recommended to drink more fluids. Ask the pharmacist about specific aqueous solutions containing sugar and salts. This recommendation is especially important for children and frail or elderly people.
- Lopamide should be taken only for the purpose it is intended for (see section 1). Under no circumstances should you exceed the maximum dose (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 the medicine).
- Stop taking Lopamide immediately and consult your doctor:
- If you suffer from AIDS and notice swelling of your abdomen.
 - If you notice difficulty defecating (constipation), swollen abdomen and/or pain.
- Tell the doctor if your condition does not improve or worsens after two days or if the diarrhea keeps recurring.

Children aged 6-12:

Use of Lopamide requires a doctor's prescription and medical supervision.

Drug interactions:

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell your doctor or pharmacist. Especially inform the doctor or pharmacist if you are taking:

- Quinidine (a medicine to treat heart rhythm disorders or malaria)
- Ritonavir (an anti-HIV medicine)
- Ketoconazole and itraconazole (medicines to treat fungal infections)
- Gemfibrozil (a medicine to reduce blood fat levels)
- Desmopressin (a medicine to treat increased urination)
- Other medicines that accelerate or slow down intestinal motility (e.g., anticholinergics)

Pregnancy and breastfeeding:

Pregnancy

If you are pregnant, think that you are pregnant or planning a pregnancy, consult the doctor or pharmacist before taking Lopamide.

Breastfeeding

Do not take this medicine during the breastfeeding period. Small amounts of the medicine might get into breast milk. Consult your doctor about an appropriate treatment for you.

Driving and operating machinery:

Lopamide may cause fatigue, drowsiness and dizziness, you may feel less alert, feel faint (lightheaded) or even faint. Do not drive or operate machinery if you experience these effects.

As for children, they should be warned against riding a bicycle or playing near roads, etc.

Important information about some of the medicine's ingredients

Each capsule contains about 87 mg of lactose. If you are sensitive to lactose, or if the doctor told you that you have intolerance to certain sugars, inform your doctor before taking this medicine.

3. How should you use the medicine?

Use the medicine according to your doctor's or pharmacist's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

Swallow the capsule with a little water.

For those with swallowing difficulties - the capsule may be opened, its contents dispersed over a small amount of food or drink and swallowed.

The standard dosage is usually:

Children from the age of 12, adolescents and adults: Start the treatment by taking 2 capsules (4 mg). If necessary, continue taking 1 capsule (2 mg) after each loose bowel movement. The maximum daily dose is 8 capsules per 24 hours (16 mg).

Do not exceed the recommended dosage.

Children aged 6-12: The dosage will be determined by the doctor only. This medicine is not intended for children and infants under the age of 6.

Stop using Lopamide when the stools return to normal, if you have no bowel movement for 12 hours or if you have constipation.

In any case, do not take Lopamide for longer than 48 hours. If there is no effect after this period, stop treatment and consult with your doctor.

If you accidentally took an overdose:

If you took an overdose, or if a child accidentally swallowed the medicine, immediately proceed to a hospital emergency room and bring the package of the medicine with you.

Symptoms of an overdose may include: increase in heart rate, irregular heartbeat, changes in heartbeat (these symptoms can have potentially serious and life-threatening consequences), you may experience drowsiness, muscle stiffness or uncoordinated body movements, difficulty breathing, and difficulty in passing urine (urinary retention). The reaction of children to high doses of Lopamide is stronger in comparison to adults. If a child took an overdose or suffers from any of the above symptoms, refer to a doctor immediately.

If you forgot to take the medicine:

Take the medicine only if necessary, in accordance with the instructions above.

If you forgot to take the medicine, take the medicine after the next loose stool. Do not take a double dose.

Do not exceed the recommended dose.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine.

Wear glasses if you need them.

If you have further questions concerning the use of the medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, the use of Lopamide may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

Stop using Lopamide and refer to a doctor immediately if you experience any of the following side effects:

Rare side effects (appear in 1-10 users out of 10,000):

- Allergic reactions, fainting, swelling of the face and throat, lips; unexplained wheezing, breathing difficulties, hives.
- Severe swelling of the abdomen or abdominal pain, severe constipation.
- Severe rash or severe irritation of the skin with redness, peeling and/or blistering (toxic epidermal necrolysis). Appearance of blisters in the mouth, eyes and genital organs.
- You experience loss of consciousness or a reduction in the level of consciousness (fainting, feeling faint or lack of alertness), uncoordinated body movements.

Stop using Lopamide and refer to a doctor as soon as possible if you experience any of the following side effects:

Uncommon side effects (appear in 1-10 users out of 1,000):

- . Itching or hives
- . Abdominal pain or swollen abdomen

Rare side effects (appear in 1-10 users out of 10,000):

- . Difficulty in passing urine
- . Severe constipation
- . Constriction of the pupils (miosis)

Additional side effects:

Common side effects (appear in 1-10 users out of 100):

- . Nausea, constipation or flatulence
- . Headache
- . Dizziness

Uncommon side effects (appear in 1-10 users out of 1,000):

- . Drowsiness or sleepiness
- . Vomiting, indigestion
- . Rash
- . Dry mouth

Rare side effects (appear in 1-10 users out of 10,000):

- . Tiredness
- . Uncoordinated body movements
- . Abnormal muscle stiffness causing poor control of body movements.

See also subsection "If you accidentally took an overdose" in section 3.

Some of the effects may be caused by the diarrhea, such as abdominal discomfort, nausea, vomiting, flatulence, dry mouth, a feeling of tiredness, sleepiness and dizziness.

If a side effect appears, or if any of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il/>

5. How should the medicine be stored?

Avoid poisoning! This medicine, like any other medicine, must be stored in a closed place out of the reach

and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor! Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.

Storage conditions: store below 25°C.

Do not discard medicines into the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, the medicine also contains the following ingredients:

Lactose, pregelatinized maize starch, magnesium stearate, dioctyl sodium sulphosuccinate, titanium dioxide (E171), indigo carmine (E132), iron oxide black (E172), iron oxide yellow (E172), erythrosin (E127), gelatin.

What does the medicine look like and what does the package contain?

Blue/yellow capsules containing a white powder, in a blister pack of 10 capsules.

Manufacturer and registration holder: Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301

Marketed exclusively by: Super-Pharm (Israel) Ltd., P.O. Box 2171, Herzliya 4672516

Medicine registration number in the National Medicines Registry of the Ministry of Health:
168-48-37078-99

Revised in November 2021 according to MOHs guidelines.