

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) – 1986**

This medicine is dispensed without a doctor's prescription
This medicine requires a doctor's prescription for children aged 6-12 years

Lopamide Capsules

Active ingredient:

Each capsule contains: Loperamide hydrochloride 2 mg

For the list of the additional 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 the doctor or pharmacist.

This medicine is not intended for children and babies under the age of 6. Use the medicine according to the instructions in the dosage section in this leaflet (section 3). Consult the pharmacist if you require additional information. Refer to a doctor if the symptoms of the illness worsen or do not improve after 48 hours.

1. What is the medicine intended for?

The medicine is intended for the control and symptomatic relief of acute diarrhea in adults, adolescents and children over the age of 6 years.

Therapeutic group: slowing 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 additional ingredients the medicine contains (listed in section 6).
- Do not use the medicine in children under the age of 6 years.
- You have a high fever or bloody stools (signs of acute dysentery).
- You suffer from an inflammation in the intestines such as 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 take medicines that reduce bowel movements.

Special warnings concerning use of the medicine

- **Before the treatment with the medicine, tell the doctor if:**
 - You suffer from a liver disease.
 - You suffer from diarrhea lasting more than 48 hours.
 - You have intolerance to certain sugars.
 - You have severe diarrhea, since your body loses more fluid, sugars and salts than usual.
 - If you are pregnant, consult your doctor before taking Lopamide.
 - Do not take this medicine during the breastfeeding period.
- The medicine treats diarrhea, but not the underlying causes of your condition. When you have diarrhea, your body loses large amounts of fluids and salts. To restore them to 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 population or elderly people.
- Consult a doctor if you have a history of medicine abuse.

- Loperamide is a type of opioid that acts directly on the bowel when used as recommended, but may cause other opioid effects when misused in high dosages. Addiction has been observed with opioids as a group.
- There have been reports of abuse and misuse of loperamide, the active ingredient in Lopamide capsules. The medicine should be taken only for the purpose for which it is intended (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 years:

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

Drug interactions:

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

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

Pregnancy and breastfeeding:

Pregnancy

If you are pregnant, think you are pregnant or are 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 pass into the breastmilk. Consult the doctor about an appropriate treatment for you.

Driving and use of machinery:

The medicine 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 have intolerance to certain sugars, inform the doctor before taking this medicine.

3. How should you use the medicine?

Use the medicine according to the doctor's or pharmacist's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine. Swallow the capsule with a little water. There is no information about opening and dispersing the capsule's contents.

The standard dosage is usually:

Children from the age of 12 years, 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).

Children aged 6-12 years: The dosage will be determined by the doctor only. **This medicine**

is not intended for children and babies under the age of 6.

Stop using Lopamide when the stools return to normal, if you have no bowel movement for the duration of 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.

Do not exceed the recommended dose.

If you accidentally took a higher dosage:

If you took an overdose or if a child has accidentally swallowed the medicine, proceed immediately 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, 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 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 the doctor or pharmacist.

4. Side effects

As with any medicine, use of Lopamide may cause side effects in some users. Do not be alarmed when 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, throat and 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.
- If you experience loss of consciousness or a reduction in level of consciousness (fainting, feeling faint or lack of alertness), muscle stiffness and uncoordinated body movements.

Side effects of unknown frequency (the frequency cannot be assessed from the available data):

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

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)

- Muscle tension (hypertonia)
- Uncoordinated movements (coordination disorder)

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, if one 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 leads to an online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

5. How to store the medicine?

- Avoid poisoning! This medicine, and 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) that appears 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:

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

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