

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

The medicine is dispensed without a doctor's prescription

This medicine requires a doctor's prescription in children between the ages of 6-12 years

## LORAMIDE 2 mg Caplets

Each caplet contains:

### Loperamide hydrochloride 2 mg

Inactive and allergenic ingredients in the preparation – see section 6 in the leaflet. See also 'Important information about some of the ingredients of the medicine' in Section 2.

**Read this leaflet carefully in its entirety before using the medicine.**

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

**This medicine is not intended for infants and children under 6 years of age.** Use it properly.

Consult a pharmacist if you need further 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?

To control and relieve symptoms of acute diarrhea.

**Therapeutic group:** Antipropulsive.

### 2. BEFORE USING THE MEDICINE

#### ❗ Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient loperamide or to any of the additional ingredients contained in the medicine (see section 6 in the leaflet).
- Do not use this medication in children under 6 years of age.
- You have high fever or bloody stools (signs of acute dysentery).
- You are suffering from an inflammation in the intestines such as ulcerative colitis.
- You are suffering 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 use of the medicine

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

- You are suffering from a liver disease.
- You are suffering from diarrhea that has lasted 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 more fluid, sugars and salts than usual.
- You are pregnant; consult your doctor before taking Loramide.
- Do not take this medicine while breastfeeding.
- Loramide 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 older people.

- Loramide 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 Loramide immediately and consult your doctor:

- If you are suffering 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 is recurrent.

#### ❗ Children aged 6 to 12:

Use of Loramide 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.** It is particularly important to 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 (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 Loramide.

#### ❗ Breastfeeding

Do not take this medicine while breastfeeding. Small amounts of the medicine may get into your milk. Consult your doctor about an appropriate treatment for you.

#### ❗ Driving and operating machinery

Loramide may cause fatigue, drowsiness and dizziness. You may feel less alert, lightheaded or even faint. Do not drive or operate machinery if you experience these effects. Children should be cautioned against riding bicycles or playing near the road and the like.

#### ❗ Important information about some of the ingredients of the medicine

Each Loramide caplet contains 118.6 mg lactose. If you have been told that you have an intolerance to sugars, inform the doctor before taking the 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 uncertain.

Swallow the caplet with a little water. Do not chew. **To remove the caplet from the blister:** tear at notch, use scissors if necessary.

The caplet may be halved or crushed and taken in a single dose.

The usual dosage is generally:

**Children from the age of 12, adolescents and adults:** Start treatment by taking 2 caplets (4 mg). If necessary, continue taking 1 caplet (2 mg) after each evacuation of loose bowel movement. The maximum daily dose is 8 caplets per day (16 mg). Do not exceed the recommended dose.

**Children ages 6-12:** The dosage will be determined by the doctor only.

This medicine is not intended for infants and children under the age of 6.

Stop using Loramide 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 Loramide for more 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 or anyone else accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

Symptoms of an overdose may include: increased 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). Children react more strongly to large amounts of Loramide than 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 dose each time you take a medicine. Wear glasses if you need them.**

**If you have further questions regarding the use of the medicine, consult the doctor or pharmacist.**

### 4. SIDE EFFECTS

As with any medicine, use of Loramide 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 this medicine and refer to a doctor immediately if you experience any of the following side effects:**

Rare side effects – occur 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 of the skin 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 level of consciousness (fainting, feeling faint or lack of alertness), uncoordinated body movements.

**Stop using Loramide and refer to a doctor as soon as possible in the following cases:**

Uncommon side effects – occur in 1-10 users out of 1,000:

- Itching or hives
- Abdominal pain or swollen abdomen

Rare side effects – occur in 1-10 users out of 10,000:

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

#### Additional side effects

Common side effects – occur in 1-10 users out of 100:

- Nausea, constipation or flatulence
- Headache
- Dizziness

Uncommon side effects – occur in 1-10 users out of 1,000:

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

Rare side effects – occur in 1-10 users out of 10,000:

- Tiredness
- Uncoordinated body movements
- Severe muscle stiffness causing poor control of body movements

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

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

#### Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://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>

In addition, you can report to Perrigo via the following address:

[www.perrigo-pharma.co.il](http://www.perrigo-pharma.co.il)

### 5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor!
- Do not use this medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 25°C.
- Do not discard medicines into the waste bin or the sink. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment.

### 6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains: Anhydrous Lactose, Pregelatinized Starch, Microcrystalline Cellulose, Hypromellose, Magnesium Stearate, Polyethylene Glycol, D&C Yellow #10 Aluminum Lake, FD&C Blue #1 Aluminum Lake, Carnauba Wax.
- What the medicine looks like and the contents of the package: An oval, greenish caplet, with a score line. The medicine comes in a blister package that contains 6, 12, 18, 24 or 30 caplets. Not all pack sizes may be marketed.
- Registration holder: Perrigo Israel Agencies Ltd., 1 Rakefet St., Shoham.
- Manufacturer: Perrigo Co., Allegan, Michigan, USA.
- Marketing: Super-Pharm (Israel) Ltd., P.O.B. 2171, Herzliya 46725.
- The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by the Ministry of Health in June 2016, and was updated in accordance with the Ministry of Health guidelines in May 2019.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 13110.30956.