

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

STOPIT Capsules

Active ingredient:

Each capsule contains: Loperamide hydrochloride 2 mg

For a list of the other ingredients, please 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.

Refer to your doctor if the symptoms get worse, or do not improve within 48 hours.

Use this medicine in the correct manner. Consult your pharmacist if you require additional information.

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

1. What is the medicine intended for?

The medicine is intended for treatment 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 the medicine contains (for a list of the other ingredients, please see section 6).
- You are suffering from diarrhea during or at the end of antibiotic treatment (in this case, contact your doctor, since this medicine must not be used if the diarrhea is caused by antibiotic treatment).
- You have symptoms of acute dysentery, which may include symptoms such as a high temperature and blood in your stools.
- You suffer from a flare-up of inflammations of the bowel such as ulcerative colitis.
- You have an intestinal infection caused by bacteria such as Salmonella, Shigella or Campylobacter.
- You are taking medicines that reduce intestinal activity.
- You suffer from constipation or swollen abdomen (particularly in children suffering from severe dehydration).
- Do not use the medicine in children under the age of 6 years.

Special warnings regarding the use of this medicine:

- Do not use this medicine frequently, or for a long period, without consulting your doctor.
- If you are sensitive to any type of food or medicine, consult your doctor before taking this medicine.
- The medicine treats diarrhea, but not its causes.
- When you suffer from diarrhea, your body loses large quantities of fluids and salts. In order to restore them to the normal levels, it is advisable that you drink more than usual, and also drink special aqueous solutions containing sugar and salts (in consultation with your

pharmacist). This recommendation is particularly important in children and frail or elderly people.

- Tell your doctor if your condition worsens, or does not improve after two days, or if the diarrhea is severe or keeps recurring.
- If you are pregnant or breastfeeding, consult your doctor before taking this medicine. See 'Pregnancy and breastfeeding' section.

Before treatment with Stopit, tell your doctor if:

- You suffer or have suffered in the past from impaired function of the liver.
- You suffer from diarrhea that lasts for more than 48 hours.

Stop taking Stopit immediately and consult your doctor if:

- You have AIDS and your stomach is swollen.
- You have difficulty with bowel movements (constipation), swollen abdomen and/or pain.

If you are taking or have recently taken any other medicines, including non-prescription medicines and nutrition supplements, please tell your doctor or pharmacist.

Especially inform your doctor or pharmacist if you are taking the following medicines (it should be noted that the following list mentions the active ingredients in the medicines. If you are not sure whether you are using one of these medicines please check with your doctor or pharmacist):

- Ritonavir (for the treatment of AIDS/against the HIV virus).
- Quinidine (used to treat heart rhythms disturbances).
- Desmopressin (for the treatment of excessive urination).
- Itraconazole or ketoconazole (for the treatment of fungal infections).
- Gemfibrozil (used to treat various problems relating to the blood fats, triglycerides and cholesterol).
- Medicines that slow down the activity of the digestive system, the stomach or intestines (such as anticholinergics or opioids) or medicines that accelerate bowel movements.
- Other medicines for treatment of diarrhea.
- Medicines that inhibit Cytochrome CYP450.

Pregnancy and breastfeeding:

If you are breastfeeding, pregnant, think you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist before using this medicine.

Driving and use of machinery:

This medicine may make you feel tired, sleepy, or dizzy. You may feel less alert, feel faint or pass out. Do not drive or operate machinery if you feel these effects.

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

Use in children:

- This medicine is not intended for children under 6 years of age.
- Use of this medicine in children aged 6-12 years requires a doctor's prescription and medical supervision.

Important information about some of the medicine's ingredients:

Each capsule contains 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 to use this medicine?

Use according to the doctor's or pharmacist's instructions. You should check with your doctor or pharmacist if you are not sure.

The standard dosage is usually:

Dosage in children and adolescents aged 12 and over, and adults:

Start the treatment with taking 2 capsules (4 mg). If necessary, continue taking one capsule (2 mg) after each loose bowel movement. The maximum daily dose is 8 tablets in 24 hours (16 mg).

Dosage in children aged 6-12 years: the dosage will be determined by the doctor only.

Do not exceed the recommended dose.

Stop using the medicine when the stools become normal again, if there is no bowel movement for 12 hours or if you are constipated. In any case, do not take Stopit for longer than 48 hours. If there is no effect after this period, stop the treatment and consult your doctor.

Directions for use:

Swallow the capsule with a small amount of water.

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

If you have accidentally taken a higher dosage: you may feel an increase in the heart rate, disturbances in the heart rate, sleepiness, muscle stiffness or uncoordinated body movements, constricted eye pupils, breathing difficulties, numbness, difficulty or inability to pass stools (constipation or intestinal obstruction) and difficulty in passing urine (urinary retention). These effects are more frequent in children.

If you have taken an overdose or if a child has accidentally swallowed the medicine, go immediately to a hospital emergency room and bring the medicine package with you.

If you forgot to take the medicine: this medicine is used only as necessary, according to the directions for use above. If you forgot to take a dose of the medicine when you should have, take the next dose after the next loose bowel movement. Do not take a double dose.

How can you contribute to the success of the treatment?

This medicine stops the diarrhea but does not treat its causes. It is important to treat the causes of the diarrhea as well, if possible.

Drink plenty of fluids (decaffeinated drinks) in order to prevent dehydration due to the diarrhea. Avoid drinking alcoholic beverages. It is recommended to eat easily digested foods. It is advisable to avoid fried or spicy foods and any food that stimulates the intestines, such as fruits and vegetables.

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.

4. Side Effects

Like any medicine, the use of Stopit may cause side effects in some users. If these side effects persist or are bothersome or get worse, please consult your doctor. Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

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

- Allergic reactions that might be severe (anaphylactic reactions) and that may appear as skin rashes, swelling of the hands, feet, face, eyes, lips, neck, throat, unexplained

wheezing, breathing difficulties/shortness of breath, fainting or a sudden drop in blood pressure.

- Abdominal swelling accompanied by pain, nausea, vomiting, inability to pass stools, signs of intestinal obstruction or megacolon.
- Severe skin rash with redness, peeling and/or blistering (for instance Stevens–Johnson syndrome, toxic epidermal necrolysis) - rare.
- Loss of consciousness or reduced level of consciousness (passing out, feeling faint or reduced alertness), uncoordinated body movements (rare).

Contact your doctor as soon as possible in the following cases:

Uncommon side effects (appear in 1-10 users out of 1,000): Itching, rash or hives; abdominal pain or abdominal swelling.

Rare side effects (appear in 1-10 users out of 10,000): Difficulty in passing urine; severe constipation; constriction of the pupils of the eyes (miosis).

Other side effects:

Common side effects (appear in 1-10 users out of 100): Nausea, constipation or flatulence; headache.

Uncommon side effects (appear in 1-10 users out of 1,000): Dizziness or sleepiness, vomiting, digestive problems; dry mouth.

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

Side effects and drug interactions in children:

Parents must inform the attending doctor of any side effect and any additional medicine given to the child. See above for detailed side effects and drug interactions.

If you experience any side effects that are not mentioned in this leaflet or if there is any change in your general feeling, consult your doctor immediately.

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads to an online form for reporting side effects, or by entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a safe place out of the reach 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.

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), erythrosine (E127), gelatin.

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

Blue/yellow capsules containing a white powder, in blister packs; 10 capsules per box.

Registration holder: Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301.

Medicine registration number in the National Medicines Registry of the Ministry of Health: 0676428224

This leaflet was checked and approved by the Ministry of Health in September 2016 and was updated according to the guidelines of the Ministry of Health in February 2018.

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