

**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

IMODIUM® Capsules

Active ingredient

Each capsule contains: Loperamide as hydrochloride 2 mg

For a list of inactive ingredients: see section 6 "Further Information". 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 children and infants under the age of 6. 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 IMODIUM AND WHAT IS IT INTENDED FOR?

Imodium is intended for the treatment 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 or to any of the additional ingredients of this medicine (appear in section 6).
- Do not use this preparation 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.
- If 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.
- If 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.
- If you are pregnant, consult your doctor before taking Imodium.
- Do not take this medicine while breastfeeding.
- Imodium 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.
- Imodium 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 Imodium 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 Imodium requires a doctor's prescription and medical supervision.

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 (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 Imodium.

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

Imodium may cause fatigue, drowsiness and dizziness, you may feel less alert, lightheaded or 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 Imodium capsule contains 127 mg lactose monohydrate. If you have been told that you have an intolerance to sugars, inform the doctor before taking the medicine.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

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 capsule with a little water. There is no information regarding opening and dispersing the contents of the capsule.

The usual dosage is generally:

Children from the age of 12, adolescents and adults: Start treatment by taking 2 capsules (4 mg). If necessary, continue taking 1 capsule (2 mg) after each evacuation of loose bowel movement. The maximum daily dose is 8 capsules 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 children and infants under the age of 6.

Stop using Imodium 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 Imodium 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 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: 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 Imodium 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 your doctor or pharmacist.

4. SIDE EFFECTS

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

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

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

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

- Itching or hives
- Abdominal pain or swollen abdomen

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

- Nausea, constipation or flatulence
- Headache
- Dizziness

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

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

Rare side effects – effects that 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 “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 occurs, or 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) that directs you to the online form for reporting side effects.

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 sight and 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 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 at a temperature of 15-30°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. FURTHER INFORMATION

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

Lactose monohydrate, maize starch, talc, magnesium stearate, erythrosine, indigo carmine, iron oxide yellow, iron oxide black, titanium dioxide and gelatin.

What Imodium looks like and the contents of the package

Capsules with a green cap and dark gray body, filled with a white powder.

Pack sizes:

A box containing 6 or 10 capsules in a blister pack.
Not all pack sizes may be marketed.

Registration Holder and Address:

J-C Health Care Ltd., Kibbutz Shefayim 6099000, Israel.

Manufacturer and Address:

Janssen Cilag, Val de Reuil, France.

This leaflet was checked and approved by the Ministry of Health in March 2018, and was updated in accordance with the Ministry of Health guidelines in August 2018.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 0251020676.

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