

## Package leaflet: Information for the user

### **Stoperan** **2 mg, hard capsules** *Loperamidi hydrochloridum*

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you notice any side effects, including any possible side effects not listed in this leaflet, talk to your doctor or pharmacist. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 days.

#### **In this leaflet:**

1. What Stoperan is and what it is used for
2. Before you take Stoperan
3. How to take Stoperan
4. Possible side effects
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6. Content of the pack and other information

#### **1. What Stoperan is and what it is used for**

Stoperan contains loperamide. It is an antidiarrhoeal. Stoperan inhibits increased bowel movements and also increases water absorption. Consequently, it slows down the passage of food through the intestines, reduces the frequency and number of bowel movements and, by causing water reabsorption in the large intestine, changes the consistency of stools. Stoperan is intended for use in adults and children over 6 years of age.

Stoperan is indicated for the symptomatic treatment of acute and chronic diarrhoea. You must talk to a doctor if you do not feel better or if you feel worse after 2 days.

#### **2. Before you take Stoperan**

##### **Do not take Stoperan if:**

- you are allergic to loperamide or any of the ingredients of this medicine (listed in section 6);
- you have conditions where slowing of intestinal peristalsis is undesirable because of the possible risk of severe complications, including intestinal obstruction, macrocolon and toxic megacolon. Stoperan should be discontinued immediately if constipation, bloating or intestinal obstruction occurs;
- you have intestinal obstruction, acute ulcerative colitis, a flare-up of haemorrhagic colitis or pseudomembranous colitis, especially after the administration of broad-spectrum antibiotics;
- you have a bacterial infection of the small intestine and colon, caused by bacteria such as *Salmonella*, *Shigella* and *Campylobacter*;
- you have acute dysentery with the symptoms of blood in your stools and a high temperature;
- it is for children under 6 years of age.

### **Warnings and precautions**

Caution should be exercised when using Stoperan in bacterial diarrhoea.

This product should be used with caution in patients with hepatic impairment due to possible toxic effects on the central nervous system.

Dehydration and electrolyte deficiency may occur in patients with diarrhoea, especially in children. Therefore, water and mineral salt deficiencies should be supplemented during diarrhoea.

Discontinue taking the product if constipation, bloating or developing intestinal obstruction occurs.

In patients with fever and blood in the stool, the causes of diarrhoea should be found before starting loperamide.

In patients with AIDS treated with Stoperan for diarrhoea, the medicine should be discontinued at the earliest sign of bloating. In patients with AIDS and concomitant infectious colitis caused by viruses and bacteria, isolated cases of toxic megacolon during the use of loperamide have been described.

Do not take this product for anything other than its intended use (see section 1) or in higher doses than recommended (see section 3). Serious heart problems (including accelerated or irregular heartbeat), have been reported in patients who took excessive doses of loperamide (the active substance of Stoperan).

### **Children and adolescents**

Stoperan is contraindicated for use in children under 6 years of age.

### **Taking other medicines**

Tell your doctor or pharmacist if you are taking or have recently taken and if you are planning to take any medicines.

Concomitant use of loperamide (16 mg in a single dose) with quinidine (a medicine used to treat cardiac arrhythmias) or ritonavir (used to treat HIV infection), which are P-glycoprotein inhibitors, results in increased plasma concentrations of loperamide. The clinical significance of these interactions is unknown.

### **Taking Stoperan with food and drink and alcohol**

It is recommended to take Stoperan with water.

Stoperan can be taken on an empty stomach or after a meal.

Stoperan taken in the doses used to treat diarrhoea virtually does not penetrate into the central nervous system; thus, the risk of interaction with alcohol is minimal.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, you need to ask your doctor or pharmacist for advice before taking this medicine.

Ask your doctor for advice before taking this medicine.

### **Driving and using machines**

Fatigue, dizziness or drowsiness may occur in the course of diarrhoea treated with loperamide.

Therefore, caution should be exercised while driving or using machines.

### **Stoperan contains lactose monohydrate**

If you have been told by your doctor that you have an intolerance to some types of sugar, contact your doctor before taking this medicine.

## **3. How to take Stoperan**

Take Stoperan as recommended in the leaflet. If you are not sure, talk to your doctor.

Stoperan should be used orally.

*Adults and children over 12 years old:*

Acute diarrhoea:

2 capsules (4 mg) initially, followed by 1 capsule (2 mg) after each loose stool. The daily dose should not exceed 8 capsules (16 mg).

Chronic diarrhoea:

1 capsule (2 mg) twice a day initially; if needed, you may increase the daily dose to 4–6 capsules (8–12 mg).

*Children aged 9 to 12:*

Acute diarrhoea:

1 capsule (2 mg) after each loose stool. The daily dose should not exceed 3 capsules (6 mg).

Chronic diarrhoea:

1 capsule (2 mg) after each loose stool. The daily dose should not exceed 3 capsules (6 mg).

*Children aged 6 to 8:*

Acute diarrhoea:

1 capsule (2 mg) after each loose stool. The daily dose should not exceed 3 capsules (6 mg).

Chronic diarrhoea:

1 capsule (2 mg) after each loose stool. The daily dose should not exceed 2 capsules (4 mg).

No dosage modification is necessary in patients with renal impairment and in elderly patients.

**Diarrhoea may subside after one dose. In that case, you should not use the medicine any longer.**

If you think the effect of Stoperan is too strong or too weak, consult your doctor.

**If you take more Stoperan than you should**

Constipation, intestinal obstruction, urinary retention and symptoms of central nervous system inhibition (increased muscle tone, stupor, confusion (disorientation), drowsiness, impaired neuromuscular coordination, pupil constriction, apnoea and respiratory depression) may occur in case of overdose. Children are more susceptible than adults to adverse central nervous system effects of the medicine.

If you have taken too many capsules, immediately contact a doctor or hospital for advice. Symptoms may include increased heart rate, irregular heartbeat, changes to your heartbeat (these symptoms can have potentially serious, life-threatening consequences), muscle stiffness, uncoordinated movements, drowsiness, difficulty urinating or weak breathing.

Children react more strongly to large amounts of Stoperan than adults. If a child takes too much of the medicine or shows any of the above symptoms, call a doctor immediately.

**Management of overdose**

If you have taken more than the prescribed dose of the medicine, consult your doctor immediately.

In case of the symptoms of overdose, a doctor may recommend naloxone as an antidote. As the action of Stoperan is longer than that of naloxone (1 to 3 hours), a repeat administration of naloxone may be indicated. Therefore, the patient should remain under strict medical supervision for at least 48 hours to detect possible central nervous system inhibition.

**If you forget to take Stoperan**

Do not take a double dose to make up for a forgotten dose.

**If you stop taking Stoperan**

Stoperan is taken as needed, so you can stop using it once you get better.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects which occur very rarely (in less than 1 in 10,000 people, including isolated cases):

- headache and dizziness, fatigue, drowsiness;
- abdominal pain, constipation, nausea and vomiting, intestinal obstruction, megacolon, including toxic megacolon, bloating with flatulence and indigestion, dry mouth;
- rash, hives and pruritus, angioedema, bullous eruptions, including Stevens-Johnson syndrome (a skin disease in which the epidermis becomes detached from the dermis), erythema multiforme (a skin disease with erythematous lesions) and toxic epidermal necrolysis (Lyell's syndrome, a skin disease in which the epidermis becomes necrotic);
- allergic reactions, sometimes severe hypersensitivity reactions, including anaphylactic shock (severe allergic reaction with sudden breathing difficulties, swelling of the face or throat and severe dizziness) and anaphylaxis-like reactions;
- urinary retention.

Many of the side effects associated with the use of loperamide are common symptoms of diarrhoeal syndromes (abdominal discomfort and pain, nausea, vomiting, dry mouth, fatigue, drowsiness, dizziness, constipation and bloating with flatulence). These symptoms are often difficult to distinguish from the side effects of the medicine used.

Some people may present other side effects during the use of Stoperan.  
If you get other side effects, not listed in this leaflet, tell your doctor.

#### Reporting of side effects

If you notice any adverse reactions, including any side effects not listed in this leaflet, please consult your doctor or pharmacist.

Side effects may be reported directly to the Pharmacovigilance Department of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products  
Al. Jerozolimskie 181C, 02-222 Warsaw; Tel + 48 22 49 21 301; Fax + 48 22 49 21 309; Website <https://smz.ezdrowie.gov.pl>

Side effects can also be reported to the Marketing Authorisation Holder

By reporting side effects, you can help provide more information about the safe use of the medicine.

#### 5. How to store Stoperan

Store at below 25°C.

Keep this medicine out of the sight and reach of children.

Do not use after the expiry date stated on the box and on the immediate pack (month/year). Blister pack labelling used, EXP: expiry date; Lot: lot number.

#### 6. Content of the pack and other information

##### What Stoperan contains

The active substance of the medicine is loperamide hydrochloride (*Loperamidi hydrochloridum*) 2 mg. Excipients are lactose monohydrate, maize starch, talc, magnesium stearate; *composition of gelatine capsule*: gelatine, erythrosine (E 127), patent blue (E 131), titanium dioxide (E 171), quinoline yellow (E 104).

##### What Stoperan looks like and contents of the pack

Hard capsule composed of a blue and a grey part, containing a white powder.

**Available packages:**

2 hard capsules in 1 blister; 4 hard capsules in 1 blister; 8 hard capsules in 1 blister; 18 hard capsules in 1 blister.

Not all pack sizes may be available on the market.

**Marketing Authorisation Holder and Manufacturer:**

US Pharmacia Sp. z o.o., ul. Ziębicka 40, 50-507 Wrocław

For more information, please contact:

USP Zdrowie Sp. z o.o., ul. Poleczki 35, 02-822 Warsaw; tel. +48 (22) 543 60 00

This leaflet was last approved: October 2020.