

## **Package leaflet: Information for the user**

### **<Invented Name> 2 mg hard capsules** loperamide hydrochloride

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. This medicine is available without prescription.**

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 get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 days.

#### **What is in this leaflet**

1. What <Invented Name> is and what it is used for
2. What you need to know before you take <Invented Name>
3. How to take <Invented Name>
4. Possible side effects
5. How to store <Invented Name>
6. Contents of the pack and other information

#### **1. What <Invented Name> is and what it is used for**

This medicine contains Loperamide which helps to stop diarrhoea by making the stools more solid and less frequent.

This medicine is used for the treatment of sudden short-lived (acute) attacks of diarrhoea in adults and children over 12 years of age. **This medicine must not be used for more than 2 days without medical advice and surveillance.**

You must talk to a doctor if you do not feel better or if you feel worse after 2 days.

#### **2. What you need to know before you take <Invented Name>**

##### **Do not take <Invented Name>**

- if you are allergic to loperamide or to any of the other ingredients in this medicine (listed in section 6). Hypersensitivity can be recognized by, for example, skin rash, itching, chest tightness or a swollen face. If you experience this, stop taking <Invented Name> and consult your doctor.
- in children under 12 years of age
- if you have a 'megacolon'(strongly dilated colon), toxic megacolon (acute toxic colitis with dilatation of the colon) and subileus (obstruction of the bowel), a serious situation that can occur in patients with Hirschsprung disease, Crohn's disease or ulcerative colitis, due to a very painful abdominal distension, fever and an accelerated heartbeat.
- if you actually have a blockage of the intestines, causing some watery stools to 'leak through'. This occurs in certain intestinal disorders.
- if you have persistent stomach pain, if you have a high temperature and / or if your stools contain mucus and / or blood. These symptoms can be caused by food poisoning or by infection or inflammation of the large intestine.
- if you have bacterial inflammation of the large and / or small intestine caused by invasive organisms, including Salmonella, Shigella and Campylobacter.

- if you have severe intestinal inflammation (eg ulcerative colitis or pseudomembranous colitis due to the use of certain antibiotics).
- In all cases where normal bowel movements should not be suppressed.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking <Invented Name>.

- With <Invented Name>, only the diarrhea itself is addressed, but not the cause of it. If the cause is known, it must be treated separately, if possible. If in doubt, always consult your doctor.
  - If you have diarrhea, you will lose a lot of fluid (dehydration). With this fluid, other important substances are also lost. Symptoms of dehydration may include dry mouth, dizziness and / or vomiting. Danger of dehydration exists especially in young children and the elderly. They should therefore be the first measure for diarrhea: supplement and maintain the fluid in the body. That means: drink a lot, and supplement sugar and salt. At the pharmacy or drugstore you can get a special salt-sugar mixture (ORS), which has to be dissolved in water. Ask your doctor or pharmacist for advice.
  - If your diarrhoea lasts for more than 48 hours stop taking the capsules and consult your doctor.
  - if you have a liver disease. <Invented Name> should only be taken after a medical advice if liver disease is present or persisted because the breakdown of loperamide may be delayed and the risk of side effects increased.
  - If you have AIDS and are treated for diarrhea with <Invented Name>. Stop <Invented Name> as soon as you experience a swollen stomach. In that case, contact your doctor. In people with AIDS and a severe intestinal infection (infectious colitis) who used loperamide (the substance also in <Invented Name>), a few cases of constipation with an increased risk of toxic megacolon have been reported. That is a heavily dilated colon, recognizable by a very painful abdominal distension, fever and an accelerated heartbeat.
  - Does your liver work less well? Then contact your doctor before using <Invented Name>. You may need to be well controlled if you use <Invented Name>. In addition, you may need a different dose to avoid side effects on the nervous system.
  - If you develop a bowel obstruction, stop taking the capsules and consult your doctor.
- Never take more than the recommended amount (see section 3). Serious heart problems (symptoms such as a rapid or irregular heartbeat) have been reported in patients who have taken too much loperamide.

### **Other medicines and <Invented Name>**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, particularly:

- ritonavir (used to treat HIV).
- quinidine (used to treat abnormal heart rhythms or malaria).
- oral desmopressin (used to treat excessive urination).
- Itraconazole or ketoconazole (used to treat fungal infections).
- gemfibrozil (used to treat high levels of lipids in the blood).

Consult a doctor before taking <Invented Name> if you use any of the above mentioned medicines.

It is to be expected that medicines with a similar mechanism of action as <Invented Name> may increase its effect and drugs that accelerate the gastrointestinal passage may reduce its effect.

### **<Invented Name> with food and drink**

You can take <Invented Name> with food and drink.

### **Pregnancy, breast-feeding and fertility**

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

**Pregnancy:** Loperamide should be avoided during the first trimester of pregnancy; however, it may be used during the second and third trimester of pregnancy.

**Breast-feeding:** This medicine is not recommended, if you are breast-feeding. Small amounts may get into your milk. Talk to your doctor about a suitable treatment.

### **Driving and using machines**

This medicine may make you feel dizzy, tired or sleepy. You may also lose consciousness, feel faint or less alert. If affected do not drive or operate machinery.

### **<Invented Name> contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## **3. How to take <Invented Name>**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

<b>Adults, the elderly and children over 12 years</b>
---

<b>How to take:</b>
---------------------

The capsules should be swallowed whole with a drink of water.
---

<b>Dose and how often to take:</b>
------------------------------------

After the first loose stool (bowel motion) take 2 capsules with water.
--

After each further loose stool, take 1 capsule.
---

Rehydration sachets are available separately.
---

- |   |
|---|
| <ul style="list-style-type: none"><li>• <b>Do not give to children under 12 years of age.</b></li><li>• Do not take more than 6 capsules in any 24 hours.</li><li>• If symptoms persist for more than 48 hours, stop taking the capsules and consult your doctor.</li><li>• <b>Replace lost fluid by drinking more liquid than usual.</b></li><li>• <b>DO NOT EXCEED THE STATED DOSE.</b></li></ul> |
|---|

### **If you take more <Invented Name> than you should**

Overdose means that you or someone in your area has taken more <Invented Name> than indicated in this leaflet (see under "How to take <Invented Name>?").

If you have taken too many <Invented Name>, 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 dry mouth, pupils of the eyes may become smaller, stomach pain, nausea, vomiting or constipation.

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

### Information for the physician in case of overdose

Signs of loperamide hydrochloride overdose may also occur after a relative overdose due to liver dysfunction. Treatment depends on the symptoms of overdose and the clinical diagnosis.

During medical follow-up, ECG monitoring for QT interval prolongation should be started.

If central nervous system symptoms occur after overdose, the opioid antagonist naloxone may be given as an antidote. As loperamide has a longer duration of effect than naloxone, repeated

administration of naloxone may be needed. The patient should therefore be closely monitored for at least 48 hours, so that possible occurrence/recurrence of overdose symptoms can be recognised.

**If you forget to take <Invented Name>**

You should only take this medicine as required following the dosage instructions carefully. If you forget to take a dose, take a dose after the next loose stool (bowel movement). Do not take a double dose to make up for a forgotten dose.

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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**Serious side effects**

**If you experience any of the following stop using the medicine and seek immediate medical help:**

Get medical help at once

**Rare: may affect up to 1 in 1,000 people**

- Allergic reactions including anaphylactic shock, unexplained wheezing, shortness of breath, swelling of the face and throat
- Loss of consciousness or reduced level of consciousness (feeling faint or less alert), increased muscle tone, coordination abnormalities
- bowel obstruction, enlargement of the colon, abdominal distension
- toxic allergic reaction at the skin and mucous membranes marked by redness, formation of blisters and detachment of the epidermis (bullous eruption (also Stevens-Johnson syndrome, Lyell syndrome and erythema multiforme)), swelling of the face, hives, itching
- Skin rashes which may be severe and include blistering and peeling of the skin.
- Widening of the large intestine (megacolon).
- A blockage in the intestine (ileus).

**Other side effects**

**If you experience any of the following stop taking the medicine and talk to your doctor:**

**Common: may affect up to 1 in 10 people**

- Headache, dizziness
- Nausea (feeling sick), constipation, flatulence (wind).

**Uncommon: may affect up to 1 in 100 people**

- Tiredness, drowsiness
- abdominal pain, abdominal discomfort, upper abdominal pain, vomiting, indigestion and heartburn, dry mouth.

**Rare: may affect up to 1 in 1000 people**

- Constriction of the pupil
- Difficulty passing water (urine)
- Fatigue.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **the national reporting system**

listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store <Invented Name>

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

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Store below 30°C.

Store in the original container in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What <Invented Name> contains

- The active substances is loperamide hydrochloride.

Each capsule, hard contains 2 mg of loperamide hydrochloride.

- The other ingredients are:

*Capsules content:* Lactose monohydrate, maize starch, talc ([E 553b](#)), magnesium stearate ([E 470b](#)).

*Capsules shell:* Titanium dioxide ([E171](#)), gelatin ([E 441](#)).

*Printing Ink:* Shellac ([E 904](#)), black iron oxide ([E172](#)).

### What <Invented Name> looks like and contents of the pack

Capsule, hard.

White opaque cap/White opaque body, size '4' hard gelatin capsule shells, imprinted with '2' on cap and 'L' on body with black ink filled with white to off-white power.

<Invented Name> hard capsules are available in clear PVC/Aluminium blisters pack.

### Pack sizes:

Blister packs: 6, 10, 12, 20, 30, 60 and 200 hard capsules.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

### This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium:	Loperamide AB 2 mg harde capsules
Czech Republic:	Loperamide Aurovitas
Germany:	Loperamid PUREN akut 2 mg Hartkapseln
Netherlands:	Loperamide HCL Sanias 2 mg, harde capsules
Poland:	Loperamide Aurovitas
Romania:	Loperamid Aurobindo 2 mg capsule

**This leaflet was last revised in {MM/YYYY}.**  
[To be completed nationally]