

## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

#### **LOPERAMIDE-2**

##### **Loperamide Hydrochloride Tablets, USP**

Read this carefully before you start taking **LOPERAMIDE-2** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **LOPERAMIDE-2**.

#### **What is LOPERAMIDE-2 used for?**

- Rapid relief of diarrhea symptoms

#### **How does LOPERAMIDE-2 work?**

LOPERAMIDE-2 makes the stools more solid and less frequent.

#### **What are the ingredients in LOPERAMIDE-2?**

Medicinal ingredient: loperamide hydrochloride

Non-medicinal ingredients: Croscarmellose Sodium, D&C Yellow No.10 Aluminum Lake, FD&C Blue No.1 Aluminum Lake, Lactose Monohydrate, Magnesium Stearate, Microcrystalline Cellulose, Povidone.

#### **LOPERAMIDE-2 comes in the following dosage forms:**

Caplet: 2 mg

#### **Do not use LOPERAMIDE-2 if:**

- there is blood in the stools or you have a fever;
- you are constipated or your abdomen is swollen or have abdominal pain;
- you have a bacterial infection in your digestive system, or suspect food-poisoning due to bacterial contamination;
- you have an inflammation of the lower bowel;
- you are taking prescription drugs that may cause constipation such as anti-psychotic and anti-depressant medications;
- you are taking antibiotics or have ulcerative colitis;
- in children less than 12 years of age, except on the advice of a doctor;
- you know you are sensitive to one of the ingredients or to any other component of this formulation (see **What are the ingredients in LOPERAMIDE-2?**);
- in doubt, ask your pharmacist or doctor for advice.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LOPERAMIDE-2. Talk about any health conditions or problems you may have,**

**including if you:**

- have mucus in the stool;
- are pregnant or breastfeeding (LOPERAMIDE-2 is not recommended for breastfeeding mothers because small amounts of loperamide can end up in your milk);
- have meningitis or liver disease, as you may need medical supervision while taking LOPERAMIDE-2;
- have a history of abnormal heart rhythm (e.g., Brugada syndrome).

**Other warnings you should know about:**

Dosage warning:

Taking more than directed can cause serious heart problems or death.

STOP USE and see your doctor or pharmacist if:

- Diarrhea gets worse, lasts longer than 48 hours or you get any unusual symptoms;
- You are infected with HIV and you have any signs of abdominal swelling or bulging.

Although LOPERAMIDE-2 stops diarrhea, it will not treat the cause of it. Whenever possible, the cause of diarrhea should also be treated.

Tiredness, dizziness, or drowsiness may occur in the setting of diarrheal symptoms treated with loperamide. Therefore, it is advisable to use caution when driving a car or operating machinery.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with LOPERAMIDE-2:**

- drugs that slow down the action of the stomach and intestines (for example, some antidepressants and cold and allergy medication), because these can make the effect of LOPERAMIDE-2 too strong.
- sedating medications
- ritonavir (used to treat HIV)
- quinidine (used to treat abnormal heart rhythms)
- oral desmopressin (used to treat excessive urination)
- itraconazole or ketoconazole (used to treat fungal infections)
- gemfibrozil (used to lower cholesterol)

**How to take LOPERAMIDE-2:**

- LOPERAMIDE-2 should be taken by the mouth. You can take it at any time of day.
- The caplets should be taken with liquid.
- When you have diarrhea, you will lose a lot of fluids. Therefore, drink plenty of clear fluids, water, unsweetened juices or clear soups.
- Do not drink alcohol or milk and avoid fruit, green vegetables and spicy or fatty foods.

These items tend to aggravate diarrhea.

**Usual dose:**

Adults (12 years and older): Take 2 caplets initially and 1 caplet every time you have a loose bowel movement, to a maximum of 8 caplets per day. Stop use if you have a solid or hard stool or if you go for 24 hours without a bowel movement.

**Overdose:**

If you think you, or a person you are caring for, have taken too much LOPERAMIDE-2, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**What are possible side effects from using LOPERAMIDE-2?**

These are not all the possible side effects you may have when taking LOPERAMIDE-2. If you experience any side effects not listed here, tell your healthcare professional.

LOPERAMIDE-2 is usually well tolerated and few undesired effects are likely when it is taken as directed.

Constipation may occur. If so, stop LOPERAMIDE-2 and if these effects are severe, consult your doctor.

Over sensitivity to LOPERAMIDE-2 is rare. It can be recognized, for instance, by skin rash or itching. If any of these signs occur, see your doctor.

The following complaints sometimes occur, but they may be due to the diarrhea itself: nausea and vomiting, tiredness, dizziness or drowsiness, dry mouth and flatulence.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>UNCOMMON</b>			
Abdominal pain		✓	✓
Difficulty urinating		✓	✓
Bloating		✓	✓
Shortness of breath		✓	✓
Swollen face		✓	✓
Abnormal coordination		✓	✓
Muscular tension		✓	✓
Pupil constriction		✓	✓
Abdominal pain upper		✓	✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

Store at room temperature between 15°C and 30°C.

Keep out of reach and sight of children.

### If you want more information about LOPERAMIDE-2:

- Talk to your healthcare professional.

- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); Or by contacting Pro Doc Ltée : 1-800-361-8559, [www.prodoc.qc.ca](http://www.prodoc.qc.ca), [medinfo@prodoc.qc.ca](mailto:medinfo@prodoc.qc.ca).

This leaflet was prepared by Pro Doc Ltée.  
Laval, Quebec, H7L 3W9

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