

PART III: CONSUMER INFORMATION

IMODIUM[®] Calming Liquid
Loperamide Hydrochloride solution

This leaflet is part III of a three-part "Product Monograph" published when IMODIUM[®] Calming Liquid was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about IMODIUM[®] Calming Liquid. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATIONWhat the medication is used for:

IMODIUM[®] Calming Liquid is used for the rapid relief of diarrhea symptoms.

What it does:

IMODIUM[®] Calming Liquid makes the stools more solid and less frequent.

When it should not be used:

You should not use IMODIUM[®] Calming Liquid if you have any of the following conditions:

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

What the medicinal ingredient is:

Loperamide hydrochloride

What the important nonmedicinal ingredients are:

carboxymethylcellulose sodium, cellulose, citric acid, D&C yellow no.10, dimethyl siloxane, FD&C blue no.1, flavour, glycerin, methylcellulose, propylene glycol, purified water, simethicone, sodium benzoate, sorbic acid, sucralose, titanium dioxide, xanthan gum.

What dosage forms it comes in:

Oral solution 2 mg/15 mL, opaque green liquid with mint odour packaged in plastic bottle.

WARNINGS AND PRECAUTIONS

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN

BEFORE you use IMODIUM[®] Calming Liquid talk to your doctor or pharmacist if you:

- have mucus in the stool;
- are pregnant or nursing a baby (IMODIUM[®] Calming Liquid is not recommended for nursing 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 IMODIUM[®] Calming Liquid;
- have a history of abnormal heart rhythm (e.g., Brugada syndrome).

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 IMODIUM[®] Calming Liquid 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.

INTERACTIONS WITH THIS MEDICATION

Always tell your doctor or pharmacist

- if you are using other drugs including herbal medicines because some drugs should not be taken together
- if you are taking 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 IMODIUM[®] Calming Liquid too strong.
- if you are taking sedating medications.

In particular, tell your doctor or pharmacist if you are taking any of the following:

- 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)

PROPER USE OF THIS MEDICATION

IMODIUM® Calming Liquid should be taken by the mouth. You can take it at any time of day. Use the attached measuring cup for accurate dosing.

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 30 mL oral solution (4 mg) initially and 15 mL oral solution every time you have a loose bowel movement, to a maximum of 120 mL oral solution (16 mg) per day.

Stop use if you have a solid or hard stool or if you go for 24 hours without a bowel movement.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

IMODIUM® Calming Liquid is usually well tolerated and few undesired effects are likely when it is taken as directed.

Constipation may occur. If so, stop IMODIUM® Calming Liquid and if these effects are severe, consult your doctor.

Over sensitivity to IMODIUM® Calming Liquid 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, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Uncommon	Abdominal pain		✓	✓
	Difficulty urinating		✓	✓
	Bloating		✓	✓
	Shortness of breath		✓	✓
	Swollen face		✓	✓
	Abnormal coordination		✓	✓
	Muscular tension		✓	✓
	Pupil constriction		✓	✓
	Abdominal pain upper		✓	✓

This is not a complete list of side effects. For any unexpected effects while taking IMODIUM® Calming Liquid, contact your doctor or pharmacist.

HOW TO STORE IT

Store IMODIUM® Calming Liquid at room temperature (15-30°C). Protect from light. Keep out of reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at
www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be obtained by contacting the sponsor, McNeil Consumer Healthcare at:
1-877-IMODIUM (1-877-466-3486)

This leaflet was prepared by McNeil Consumer Healthcare, division of Johnson & Johnson Inc.

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