

PART III: CONSUMER INFORMATION

IMODIUM[®] Caplets, Quick-Dissolve Tablets, Calming Liquid & LIQUI-GELS[®] Loperamide Hydrochloride

This leaflet is part III of a three-part "Product Monograph" published when IMODIUM[®] 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[®]. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

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

What it does:

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

When it should not be used:

You should not use IMODIUM[®] 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:

Caplets: Each light green, capsule-shape tablet, embossed "IMODIUM A-D" on one side, and "2 mg" on the other side, contains the following nonmedicinal ingredients (alphabetical): cellulose, colloidal silicon dioxide, D&C yellow No. 10, dibasic calcium phosphate, FD&C blue No. 1, and magnesium stearate.

Quick-Dissolve tablets: Each white, circular tablet contains the following nonmedicinal ingredients (alphabetical): aspartame, flavour, gelatin, mannitol and sodium bicarbonate.

Calming Liquid: The Calming Liquid is an opaque, green liquid with a mint odour, packaged in plastic bottles. Nonmedicinal

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ingredients (alphabetical): 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.

LIQUI-GELS[®]: Each blue-coloured, liquid filled capsule contains the following nonmedicinal ingredients (alphabetical): FD&C blue No. 1, gelatin, glycerol, propylene glycol, propylene glycol monocaprylate, soya lecithin, triglycerides and water.

What dosage forms it comes in:

2 mg caplet, 2 mg Quick-Dissolve tablet, 2 mg/15 mL Calming Liquid (oral solution) and 2 mg LIQUI-GELS[®] .

WARNINGS AND PRECAUTIONS

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN

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

- are pregnant or nursing a baby. IMODIUM[®] 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[®].

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[®] 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.

Taking more than directed may cause serious heart problems leading to death.

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[®] 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[®] should be taken by the mouth. You can take IMODIUM[®] at any time of day. The caplets and LIQUI-GELS[®] capsules should be taken with liquid. The Quick-Dissolve tablet is a fast-dissolving tablet which can be taken without fluid. The tablet disintegrates within seconds on the surface of the tongue and is then swallowed with the saliva. The Quick-Dissolve tablets should not be pushed through the blister, as this would damage them. To take the tablets out of the blister, pull up the edge of the foil, tear the foil completely off, press out and then remove the tablet. The dose for the Calming Liquid should be administered with the attached measuring cup only.

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 or 2 tablets or 2 capsules or 30 mL oral solution (4 mg) initially and 1 caplet or 1 tablet or 1 capsule or 15 mL oral solution every time you have a loose bowel movement, to a maximum of 8 caplets or 8 tablets or 8 capsules or 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[®] is usually well tolerated and few undesired effects are likely when it is taken as directed.

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

Over sensitivity to IMODIUM[®] 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[®], contact your doctor or pharmacist.

HOW TO STORE IT

Store IMODIUM[®] LIQUI-GELS[®], caplets and oral solution at room temperature (15-30°C). Protect from light. Store IMODIUM[®] Quick-Dissolve tablets at room temperature (15-30°C) and protect from moisture. 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)

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