

PART III: CONSUMER INFORMATION**IMODIUM[®] Complete** Caplets and Chewable Tablets
Loperamide Hydrochloride and Simethicone

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

ABOUT THIS MEDICATIONWhat the medication is used for:**IMODIUM[®] Complete:**

- Provides effective diarrhea relief in adults and children 12 years and over;
- *Offers an effective medicine to relieve abdominal pain, bloating and cramping associated with gas.*

What it does:

IMODIUM[®] Complete provides rapid relief of diarrhea by making the stools more solid and less frequent PLUS relieves gas, cramps and bloating.

When it should not be used:

You should not use IMODIUM[®] Complete 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 you have difficulty swallowing;
- if in doubt, ask your pharmacist or doctor for advice.

What the medicinal ingredient is:

Each caplet or chewable tablet contains: loperamide hydrochloride 2 mg and simethicone 125 mg.

What the important nonmedicinal ingredients are:

Caplets: acesulfame potassium, croscarmellose sodium, dibasic calcium phosphate, flavour, maltodextrin, microcrystalline cellulose, propylene glycol, stearic acid.

Chewable Tablets: basic polymethacrylates, cellulose acetate, corn starch, D&C yellow no. 10, dextrates, FD&C blue no. 1 aluminum

lake, microcrystalline cellulose, N&A vanilla mint flavour, sorbitol, sodium saccharin, stearic acid, sucrose, tribasic calcium phosphate.

What dosage forms it comes in:

Caplets (capsule-shaped tablet) or a pleasant tasting chewable tablet that is convenient for travelling.

WARNINGS AND PRECAUTIONS**KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN**

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

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

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[®] Complete 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[®] Complete 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[®] Complete should be taken by mouth and can be taken at any time of day. The caplets should be taken with a full (250 mL) glass of water. The chewable tablets should be chewed fully and then swallowed.

When you have diarrhea,

- you will lose a lot of fluids. Therefore, drink plenty of clear fluids, water, unsweetened juices or clear soups.
- Take the caplets only on an empty stomach (1 hour before or 2 hours after a meal).
- 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): Swallow 2 caplets or chew 2 tablets initially and 1 caplet or chewable tablet every time you have a loose bowel movement, to a maximum of 4 caplets or chewable tablets per day. Do not exceed the recommended dose. Stop use if you have a solid or hard stool or if you go for 24 hours without a bowel movement.

IMODIUM[®] Complete is not recommended for children under 12 years except on the advice of a doctor.

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[®] Complete is usually well tolerated and few undesired effects are likely when it is taken as directed.

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

Oversensitivity to IMODIUM[®] Complete 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 |
|------------------|-------------------------------------|---------------------------------------|
| | | |

| | | Only if severe | In all cases | or pharmacist |
|----------|-----------------------|----------------|--------------|---------------|
| 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[®] Complete, contact your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature (15-30°C). Keep out of reach of children.

REPORTING SIDE EFFECTS

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](#);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 0701E
Ottawa, ON K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

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.

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

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