

## **PATIENT MEDICATION INFORMATION**

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

#### **IMODIUM® Complete**

#### **Loperamide Hydrochloride / Simethicone Tablets**

Read this carefully before you start taking **IMODIUM® Complete** 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 **IMODIUM® Complete**.

#### **What is IMODIUM® Complete used for?**

- 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.

#### **How does IMODIUM® Complete work?**

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

#### **What are the ingredients in IMODIUM® Complete?**

Medicinal ingredients: loperamide hydrochloride 2 mg, simethicone 125 mg

Non-medicinal ingredients: acesulfame potassium, croscarmellose sodium, dibasic calcium phosphate, flavour, maltodextrin, microcrystalline cellulose, propylene glycol, stearic acid

#### **IMODIUM® Complete comes in the following dosage forms:**

Caplets (capsule-shaped tablets)

#### **Do not use IMODIUM® Complete 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;
- you know you are sensitive to one of the ingredients or to any other component of this formulation (see **What are the ingredients in IMODIUM® COMPLETE?**);
- you have difficulty swallowing;
- 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 IMODIUM® Complete. Talk about any health conditions or problems you may have, including if you:**

- have mucus in the stool;
- are pregnant or breastfeeding (IMODIUM® Complete 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 IMODIUM® Complete;
- 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 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.

**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 IMODIUM® Complete:**

- drugs that slow down the action of the stomach and intestines (for example, some antidepressants and cold and allergy medication); these can make the effect of IMODIUM® Complete 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 IMODIUM® Complete:**

- 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.
- 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 initially and 1 caplet every time you have a loose bowel movement, to a maximum of 4 caplets 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:**

If you think you, or a person you are caring for, have taken too much IMODIUM® Complete, 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 IMODIUM® Complete?**

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

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.

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop taking drug and get immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
<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.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 (15-30°C).

Keep out of reach and sight of children.

**If you want more information about IMODIUM® Complete:**

- 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>); the manufacturer's website [www.imodium.ca](http://www.imodium.ca), or by calling 1-877-IMODIUM (1-877-466-3486).

This leaflet was prepared by McNeil Consumer Healthcare.

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