

# Imodium®

## CLASSIC 2mg CAPSULES

### Loperamide hydrochloride

- This medicine is used to treat sudden short-lived (acute) attacks of diarrhoea in adults and children aged 12 years and over. It can also be used to treat diarrhoea associated with Irritable Bowel Syndrome (IBS) in adults aged 18 years and over after your doctor has diagnosed you are suffering from this condition.
- **Do not take this medicine:**
  - There are some people who should not use this medicine. *To find out if you are one of them. See Section 2 ▶*
  - If you have ever had a **bad reaction** to any of the ingredients. *For the list of ingredients. See Section 6 ▶*
- **Speak to your doctor:**
  - If you suffer from any of the conditions mentioned in *Section 2 ▶*
  - If you are taking any **other medicines**. See *Section 2 ▶*
- **Follow the dosage instructions carefully.** These are shown in the dosage tables. See *Section 3 ▶*

**Now read this whole leaflet carefully before you use this medicine.** Keep the leaflet: you might need it again.

## 1 What the medicine is for

Imodium is a medicine which is used to treat sudden short-lived (acute) attacks of diarrhoea in adults and children aged 12 years and over. It can also be used to treat diarrhoea associated with Irritable Bowel Syndrome (IBS) in adults aged 18 years and over after your doctor has diagnosed you are suffering from this condition.

The capsules contain loperamide hydrochloride which helps reduce diarrhoea by slowing down an overactive bowel, which helps the body to absorb water and salts from the bowel.

## 2 Before taking this medicine

This medicine is suitable for most people, but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

### X Do not take this medicine...

- If you have ever had a **bad reaction** to any of the ingredients.
- If it is for a **child under 12 years old**.
- If you have **severe diarrhoea** after taking antibiotics.
- If you are having a flare up of an **inflammatory bowel** condition like **ulcerative colitis**.
- If you are **constipated** or your **stomach appears swollen** (particularly in children with severe dehydration).
- If you have **acute dysentery**, the symptoms of which may include **blood in your stools** and a **high temperature**.

If any of these apply to you, **get advice from a doctor or pharmacist without taking Imodium Capsules.**

### ! Talk to your doctor or pharmacist...

- If you have **AIDS** and your **stomach becomes swollen**, stop taking the capsules immediately and contact your doctor.
- If you suffer from **liver problems**.
- If your diarrhoea lasts for **more than 24 hours** (or **2 weeks** if your diarrhoea is related to IBS).
- If you have been told by your doctor that you have an **intolerance to some sugars**.
- If you have **severe diarrhoea** as your body loses more fluid, sugars and salts than normal.
- If you are taking any **other medicines**, including:
  - *ritonavir* (used to treat **HIV**) or *quinidine* (used to treat **abnormal heart rhythms** or **malaria**).

If you are unsure about any of the medicines you are taking, show the bottle or pack to your pharmacist.

If any of these bullet points apply to you now or in the past, **talk to a doctor or pharmacist.**

### ! If you are pregnant or breast-feeding

- Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant, think you are pregnant or planning to become pregnant.
- Do not take this medicine if you are breast-feeding as small amounts may get into your milk. Talk to your doctor about a suitable treatment.

### ! Special warnings about this medicine

- This medicine may make you feel dizzy, tired or sleepy. If affected do not drive or operate machinery.
- Imodium Capsules only treat the symptoms of diarrhoea. When you have diarrhoea, your body can lose large amounts of fluids and salts. You will need to replace the fluid by drinking more liquid than usual. Ask your pharmacist about special powders (known as **oral rehydration therapy**) which replace fluids and salts lost during diarrhoea. The prevention of fluid depletion (dehydration) is of particular importance in infants, children and frail and elderly people with acute diarrhoea.
- You can use Imodium Capsules for diarrhoea associated with IBS which has been diagnosed by your doctor. If your symptoms change or you are concerned about anything you should talk to your doctor.
- If your IBS related diarrhoea continues for longer than 2 weeks you should talk to your doctor.

### ! Some of the ingredients can cause problems

- This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicinal product.



### 3 How to take this medicine

Check the tables below to see how much medicine to take.

- Swallow the correct number of capsules whole with a drink of water.
- For oral use only.
- Do not use more than the stated dose shown in the tables below.

#### **i** Children under 12 years old

This medicine is not recommended for children under 12 years old.

#### **i** Adults and children 12 years and over To treat sudden short-lived (acute) diarrhoea:

Age	Dose
Adults and children aged 12 years and over	Swallow <b>two capsules</b> initially, followed by <b>one capsule</b> after each loose bowel movement.

- Do not take more than 8 capsules in any 24 hour period.
- If symptoms persist for more than 24 hours talk to your doctor.

#### **i** Adults aged 18 years and over

To treat diarrhoea associated with Irritable Bowel Syndrome already diagnosed by a doctor:

Age	Dose
Adults aged 18 years and over	Swallow <b>two capsules</b> initially. Further loose bowel movements may be controlled by taking <b>one or two capsules</b> depending on the severity of your symptoms.

- Do not take more than 8 capsules in any 24 hour period.
- If your symptoms change, or if your diarrhoea persists for more than 2 weeks, talk to your doctor.

#### **!** If anyone takes too much of this medicine

If anyone takes too many Imodium Capsules, contact your doctor or nearest Accident and Emergency department (Casualty) taking this leaflet with you.

#### **!** If you forget to take the medicine

You should only take this medicine as required following the dosage instructions above carefully. If you forget to take a dose, take a dose after the next loose stool (bowel movement). **Do not** take a double dose.

### 4 Possible side-effects

Imodium Capsules can have side-effects, like all medicines, although these don't affect everyone and are usually mild.

#### If you experience any of the following, stop using the medicine and seek immediate medical help:

- Very rarely:** (less than 1 in 10,000 people are affected)
- Allergic reactions including unexplained wheezing, shortness of breath, passing out or swelling of face and throat.
  - Skin rashes which may be severe and include blistering or peeling of the skin.

#### If you experience any of the following, stop using the medicine and talk to your doctor:

- Very rarely:** (less than 1 in 10,000 people are affected)
- Itchiness or hives.
  - Difficulties passing water.
  - Stomach pain or swollen stomach.
  - Severe constipation.

#### Other effects which may occur include:

- Very rarely:** (less than 1 in 10,000 people are affected)
- Dizziness or drowsiness.
  - Feeling sick, vomiting, indigestion, constipation or wind.

#### Other effects reported include:

- Tiredness.
- Dry mouth.

If you experience any side-effects not included in this leaflet or are not sure about anything, **talk to your doctor or pharmacist.**

### 5 Storing this medicine

Keep the product out of the reach and sight of children.

Do not use your medicine after the date shown as the expiry date on the packaging.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### 6 Further information

#### What's in this medicine?

**The active ingredient in Imodium Capsules is:** Loperamide hydrochloride 2 mg per capsule.

**Other ingredients are:** Lactose, maize starch, talc and magnesium stearate (E572). The capsule itself is made up of titanium dioxide (E171), black ferrous oxide (E172), yellow ferric oxide (E172), indigo carmine (E132), erythrosine (E127) and gelatin.

#### What the medicine looks like

Imodium Capsules are green / grey capsules marked 'Imodium' and 'JANSSEN'. They are available in packs of 8, 12 or 18 capsules.

#### Product Licence holder:

McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG, UK.

#### Manufacturer:

Janssen-Cilag SA, Campus de Maigremont, 27100 Val de Reuil, France

#### This leaflet was revised November 2009.

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