

PACKAGE LEAFLET: INFORMATION FOR THE USER

Imodium® Instants 2mg Orodispersible Tablets (loperamide hydrochloride)

Your medicine is available using the name Imodium Instants 2mg Orodispersible Tablets but will be referred to as Imodium Instants throughout this leaflet.

- This medicine is used to treat sudden short-lived (acute) attacks of diarrhoea in adults and children aged 12 years and over.
- **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 are allergic to loperamide or any of the other ingredients of this medicine.
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 table. *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 Instants is a medicine which is used to treat sudden short-lived (acute) attacks of diarrhoea in adults and children aged 12 years and over. The tablets 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. Imodium Instants should be used in conjunction with oral rehydration therapy which replace fluids and salts lost during diarrhoea.

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.

Do not take this medicine...

- If you are allergic to loperamide or any of the other ingredients of this medicine (listed in section 6).
- 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 you have had a **bacterial infection** of the small intestine or colon.
- If you have a **blockage of the bowel**, including a blockage due to paralysis of the bowel wall.
- If you have an **enlargement of the colon**, particularly if this enlargement is very rapid.

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

Warnings and Precautions

- Imodium Instants only treats the symptoms of diarrhoea. Whenever the cause can be identified, it should be treated appropriately.
- If you have **AIDS** and your **stomach becomes swollen**, stop taking the tablets immediately and contact your doctor.
- If you suffer from **liver disease**.
- If your diarrhoea lasts for **more** than 24 hours, please consult your doctor.
- If you have **severe diarrhoea** as your body loses more fluid, sugars and salts than normal.
- If you are taking any **other medicines**, including:

Other medicines

- *ritonavir* (used to treat **HIV**) or *quinidine* (used to treat **abnormal heart rhythms** or **malaria**).
- *itraconazole* or *ketconazole* (**antifungal** medicines)
- *gemfibrozil* (used to treat **high cholesterol**)
- *oral desmopressin* (used to **control thirst** and **urine production** in patients with diabetic insipidus)

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.

Driving and using machines

- This medicine may make you feel dizzy, tired or sleepy. If affected, do not drive or operate machinery.

Other information about this medicine

- Imodium Instants 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.

Some of the ingredients can cause problems

- Aspartame (E951) contains a source of phenylalanine which may be harmful for people with phenylketonuria.

3. How to take this medicine

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

- Peel back the lid and tip the tablet out. Do not push the tablets through the lid.
- Place the correct number of tablets on the tongue. The tablets dissolve quickly in your mouth, so you don't need water to swallow them. Do not chew.
- For oral use only.
- Do not use more than the stated dose shown in the tables.

Children under 12 years old

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

Adults and children 12 years and over

To treat sudden short-lived (acute) diarrhoea:

Age	Dose
Adults and children aged 12 years and over	Take two tablets initially, followed by one tablet after each loose bowel movement.
▪	Do not take more than 5 tablets in any 24 hour period.
▪	If symptoms persist for more than 24 hours talk to your doctor.

Use in the elderly, patients with kidney or liver problems

No dose adjustment is required for the **elderly** or patients with **kidney** problems. However, if you have **liver** problems you should speak to your doctor or pharmacist before taking this medicine.

If anyone takes too much of this medicine

If anyone takes too many Imodium Instants tablets, contact your doctor or nearest Accident and Emergency department 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 Instants 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:

Rarely: (less than 1 in 1,000 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.
- Loss of consciousness or reduced level of consciousness.

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

Common: may affect up to 1 in 10 people

- Headache
- Constipation
- Nausea
- Flatulence

Uncommon: may affect up to 1 in 100 people

- Dizziness or drowsiness
- Feeling sick, vomiting, indigestion, constipation or wind
- Tiredness
- Dry mouth
- Stomach discomfort
- Rash

Rarely: less than 1 in 1,000 people are affected

- Itchiness or hives
- Difficulties passing water
- Stomach pain or swollen stomach
- Severe constipation
- Hypertonia (muscle tension)
- Miosis (constriction of the eye pupil)
- Ileus (blockage of the bowel, this may be due to paralysis of the bowel wall)
- Megacolon (enlargement of the colon, this may be rapid)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. Storing this medicine

Keep **this medicine** out of the sight and reach of children.

Do not use your medicine after the date shown as the expiry date (Exp) printed on the carton and on the blister.

Store in the original package.

If your medicine appears to be discoloured or show any other signs of deterioration, please return to your pharmacist who will advise you further.

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?

Each tablet contains 2mg loperamide hydrochloride.

Also contains gelatin, mannitol (E421), aspartame (E951), sodium hydrogen carbonate and mint flavour.

What the medicine looks like

Imodium Instants come in the form of white to off-white, **circular, freeze-dried tablets**.

Imodium Instants are available in blister packs of 12 tablets.

Manufacturer

Manufactured by: Janssen-Cilag SpA, Via Constant Janssen, Borgo San Michele, Latina, Italy.

Procured from within the EU by the Parallel Product Authorisation holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

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