

Package leaflet: Information for the patient

Imodium® Instants 2 mg Orodispersible Tablets loperamide hydrochloride

Read all of this leaflet carefully because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- This medicine is available without prescription and is used to treat sudden short-lived (acute) attacks of diarrhoea in adults and children aged 12 years and over.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4 ►.
- You must talk to a doctor if you do not feel better or if you feel worse after 24 hours.

What is in this leaflet

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2. What you need to know before you take IMODIUM® Instants
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1. What IMODIUM® Instants is and what it is used 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.

You must talk to a doctor if you do not feel better or if you feel worse after 24 hours in case of acute diarrhoea.

2. What you need to know before you take IMODIUM® Instants

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 IMODIUM® Instants...

- 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

Talk to your doctor, pharmacist or nurse before taking IMODIUM® Instants.

- 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.
- Do not take this product for anything other than its intended use (see section 1) and never take more than the recommended amount (see section 3). Serious heart problems (symptoms of which include fast or irregular heartbeat) have been reported in patients who have taken too much loperamide, the active ingredient in IMODIUM® Instants.

Other medicines and IMODIUM® Instants

- Tell your doctor or pharmacist if you are using, have recently used or might use **any other medicines**.
- ritonavir (used to treat **HIV**) or quinidine (used to treat **abnormal heart rhythms** or **malaria**).
- itraconazole or ketoconazole (**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**.

⚠ Pregnancy and breast-feeding

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
- 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.

⚠ IMODIUM® Instants contains Aspartame and Mint Flavour

- This medicine contains Aspartame (E951). Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.
- Mint flavour contains traces of sulphites. This may rarely cause severe hypersensitivity reactions and bronchospasm.
- This medicine contains 0.00066 mg benzyl alcohol (from mint flavour) in each dose (2 mg) which is equivalent to 0.00033 mg/mg. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you have a liver or kidney disease, or if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).
- This medicine contains less than 0.00003 mg of alcohol (ethanol) in each tablet. The small amount of alcohol in this medicine will not have any noticeable effects.
- This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

The drug Imodium Instant contains glucose, which is a component of maltodextrin found in the mint flavour composition:

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 IMODIUM® Instants

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 you take more IMODIUM® Instants than you should

If you have taken too many IMODIUM® Instants, immediately contact a doctor or hospital for advice. Symptoms may include: increased heart rate, irregular heartbeat, changes to your heartbeat (these symptoms can have potentially serious, life-threatening consequences), muscle stiffness, uncoordinated movements, drowsiness, difficulty urinating, or weak breathing.

Children react more strongly to large amounts of IMODIUM® Instants than adults. If a child takes too much or shows any of the above symptoms, call a doctor immediately.

⚠ If you forget to take IMODIUM® Instants

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 to make up for a forgotten tablet.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

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.
- Not known (frequency cannot be estimated from the available data):
Upper abdominal pain, abdominal pain that radiates to back, tenderness when touching the abdomen, fever, rapid pulse, nausea, vomiting, which may be symptoms of inflammation of the pancreas (acute pancreatitis).

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).
- Coordination abnormality (uncoordinated movements).
- 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).
- Glossodynia (burning sensation in the mouth).

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, HPRAs Pharmacovigilance, website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store IMODIUM® Instants

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

Store in the original packaging.

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

Do not throw away any medicines via household waste.

Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What IMODIUM® Instants contains

The active ingredient in IMODIUM® Instants is: Loperamide hydrochloride 2 mg per tablet.

Other ingredients are: gelatin, mannitol (E421), aspartame (E951), sodium hydrogen carbonate and mint flavour.

What IMODIUM® Instants looks like and contents of the pack

IMODIUM® Instants come in the form of white, orodispersible (dissolve in the mouth) tablets available in packs of 12.

Parallel Product Authorisation holder

IMED Healthcare Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland.

Manufactured by

Janssen-Cilag, Domaine de Maigremont, 27100 Val de Reuil, France.

Repackaged by

Cast Healthcare Ltd, Unit E, The Business Centre, 5-7 Tobermore Road, Draperstown, Magherafelt, BT45 7AG, UK(NI) or IMED Healthcare Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland.

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