



- This medicine is used to treat sudden short-lived (acute) attacks of diarrhoea and calm additional abdominal discomfort such as cramps, wind and bloating.
- This medicine is for use by 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 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.** Children and adults need different amounts. 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® Plus Comfort tablets is a medicine which is used to treat sudden short-lived (acute) attacks of diarrhoea and calm additional abdominal discomfort such as cramps, wind and bloating. 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. The tablets also contain simeticone, which is an anti-foaming agent that breaks up trapped wind in the bowel that causes cramps and bloating. This medicine is for use in adults and children aged 12 years and over.

2 Before taking this medicine

This medicine is suitable for most adults and children aged 12 years and over, 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 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**.
 - 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® Plus Comfort tablets.**

⚠ **Talk to your doctor or pharmacist...**

- 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 48 hours**.
- If you have **severe diarrhoea** as your body loses more fluid, sugars and salts than normal.
- If you are taking any **other medicines**, including:
 - *quinidine (used to treat abnormal heart rhythms or malaria)*
 - *itraconazole or ketoconazole (antifungal medicines)*
 - *gemfibrozil (used to treat high cholesterol)*
 - *ritonavir (used to treat HIV infection and AIDS)*
 - *desmopressin (used to control thirst and urine production in patients with diabetes 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.

⚠ **Special warnings about this medicine**

- This medicine may make you feel dizzy, tired or sleepy. If affected do not drive or operate machinery.
- IMODIUM® Plus Comfort tablets only treat the symptoms of diarrhoea. In some cases, the cause of your diarrhoea may require treatment. If symptoms persist or worsen, please contact your doctor. 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.
- 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® Plus Comfort tablets.

⚠ **Some of the ingredients can cause problems**

- This medicine contains <0.044 mg benzyl alcohol in each tablet which is equivalent to <0.000046 mg/mg. Benzyl alcohol may cause allergic reactions.
- This medicine contains 25 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 1.25% of the recommended maximum daily dietary intake of sodium for an adult.

3 How to take this medicine

Check the table overleaf to see how much medicine to take.

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



Children under 12 years old

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

Adults and children 12 years and over

Age	Dose
Adults over 18 years old	Swallow two tablets initially, followed by one tablet after each loose bowel movement.
Children and young adults (12 to 18 years)	Swallow one tablet initially, followed by one tablet after each loose bowel movement.
<ul style="list-style-type: none"> Do not take more than 4 tablets in any 24 hour period. Do not take for more than 48 hours. If symptoms persist for more than 48 hours talk to your doctor. 	



If anyone takes too much of this medicine

If you have taken too many IMODIUM® Plus Comfort tablets, 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, weak breathing, dry mouth or the pupils of your eyes may become small, stomach pains, feel sick or vomit or be constipated.

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



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® Plus Comfort tablets 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:

Allergic reactions including swelling of the face, tongue or throat, difficulty swallowing, unexplained wheezing, shortness of breath which may be accompanied by skin rash or hives.

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

- Difficulties passing water
- Severe abdominal pain, abdominal bulging or swelling or fever which may be due to a blocked or enlarged bowel
- Severe constipation

Other effects which may occur include:

Common side-effects:

(less than 1 in 10 but more than 1 in 100 people get these):

- Headache
- Feeling sick
- A change in the way some things taste

Uncommon side-effects:

(less than 1 in 100 but more than 1 in 1000 people get these):

- Drowsiness
- Dizziness
- Weakness
- Constipation
- Vomiting
- Indigestion
- Wind
- Dry mouth
- Rash

Rare side-effects:

(less than 1 in 1000 but more than 1 in 10 000 people get these):

- Loss of consciousness or decreased consciousness
- Excessive contraction of the pupil of the eye
- Skin rash, which may lead to severe blistering and peeling of the skin
- Hives
- Itching
- Tiredness

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5 Storing this medicine

Keep the product out of sight and reach of children.

This medicinal product does not require any special storage conditions.

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 protect the environment.

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

6 Further information

What's in this medicine?

The active ingredients in IMODIUM® Plus Comfort tablets are: Loperamide hydrochloride 2 mg and simeticone (equivalent to 125 mg dimeticone) per tablet.

Other ingredients are: Calcium hydrogen phosphate anhydrous, microcrystalline cellulose, acesulfame K, artificial vanilla flavour (includes propylene glycol, maltodextrin and benzyl alcohol), sodium starch glycolate (type A) and stearic acid.

What the medicine looks like

IMODIUM® Plus Comfort tablets are white capsule shaped tablets marked with a line between “2” and “125” on one side and “**IMO**” on the other side available in packs of 6.

Product Licence holder:

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

Manufacturer:

Janssen-Cilag SpA Via C.Janssen, Borgo San Michele, Latina, Italy.

This leaflet was revised November 2018.

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