

Imodium®

IBS Relief 2mg Soft Capsules
Loperamide hydrochloride

- If your doctor has confirmed that you have **Irritable Bowel Syndrome (IBS)**, this product can help you treat attacks of IBS diarrhoea associated with this condition. See also *Section 2* Extra Warnings for IBS patients. ▶
- This medicine can also be used to treat short-term diarrhoea. The **age limit** and **treatment period** for this is different. See *Section 1* ▶
- **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.** 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® IBS Relief 2 mg Soft Capsules is used to treat **two types of diarrhoea**. The two types have different age limits.

i IBS diarrhoea

- For adults and young people aged **18 and over** who have been diagnosed with IBS (Irritable Bowel Syndrome).
- To treat attacks that last up to **48 hours**.
- You can use this medicine for **up to 2 weeks** for repeated attacks, but if any one attack lasts continuously for **longer than 48 hours, talk to your doctor**.

i Short-term diarrhoea

- For adults and children aged **12 and over**.
- To treat attacks that last up to **48 hours**.
- If your attack lasts longer than 48 hours, **talk to your doctor**.

The capsules contain loperamide hydrochloride, a substance that helps reduce diarrhoea by slowing down an overactive bowel. This allows water and salts that are usually lost in diarrhoea to be absorbed by the body.

2 Before taking this medicine

i Warnings for everyone

This medicine is suitable for most people, but a few people should not use it:

X Do not take this medicine...

- If you have ever had a **bad reaction** to any of the ingredients.
- If you are under 18 years for an IBS patient (or under 12 years for short-term diarrhoea).
- 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** (especially 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 applies to you, **talk to a doctor or pharmacist and do not take IMODIUM®**.

A Talk to your doctor first...

- If you have **AIDS** and your **stomach becomes swollen**, stop taking the capsules immediately and contact your doctor.

- If you suffer from **liver disease**.
- If you have diarrhoea that 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:
 - *ritonavir* (used to treat **HIV**).
 - *quinidine* (used to treat **abnormal heart rhythms** or **malaria**).
 - *oral desmopressin* (used to treat **excessive urination**).
 - *itraconazole* or *ketoconazole* (used to treat **fungal infections**).
 - *gemfibrozil* (used to treat **high cholesterol**).

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

If any of these applies to you (now or in the past), **talk to a doctor or pharmacist**.

Pregnancy or breast-feeding

- **If you are pregnant**, think you are pregnant or planning a pregnancy: ask your doctor or pharmacist for advice before taking this medicine.
- **If you are breast-feeding** do not take this medicine. 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. You may feel less alert, feel faint or pass out. If you're affected do not drive or use machines.
- Your body can lose large amounts of fluids and salts when you have diarrhoea. You need to replace the fluid by drinking more liquid than usual. Ask your pharmacist about **rehydration therapy** to replace lost salts. **This is especially important for children, and frail or older people**.
- Consult with a doctor if you have a history of drug abuse.
- Loperamide is a type of opioid that acts directly on the gut when used as recommended but can cause other opioid effects when misused at high doses. Addiction is observed with opioids as a class.
- Abuse and misuse of loperamide, the active ingredient in IMODIUM® IBS Relief 2mg Soft Capsules, have been reported. 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® IBS Relief 2mg Soft Capsules.

Some of the ingredients can cause problems

- IMODIUM® IBS Relief 2 mg Soft Capsules contain **soya lecithin**. If you are allergic to **soya** or **peanut**, do not use this medicinal product.

- This medicine contains 115.31 mg Propylene Glycol in each capsule which is equivalent to 0.65 mg/mg.
- This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

i Extra warnings for IBS patients

Use only if your doctor has previously diagnosed IBS. Check the following:

X Do not take this medicine...

- If you are aged **under 18**.

A Talk to your doctor first...

- If you are aged **40 or over** and it is **some time since your last IBS attack**.
- If you are aged **40 or over** and your **IBS symptoms are different** this time.
- If you have recently **passed blood from the bowel**.
- If you suffer from **severe constipation**.
- If you are feeling **sick or vomiting**.
- If you have **lost your appetite or lost weight**.
- If you have **difficulty or pain passing urine**.
- If you have a **fever**.
- If you have **recently travelled abroad**.

If any of these applies to you, **talk to your doctor before taking IMODIUM®**.

Turn over ▶

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. Do not chew. For oral use only.
- Do not use more than the dose shown in the tables.
- The capsules are not for long-term treatment.

IBS diarrhoea

Age	Dose
Adults aged 18 and over	Take two capsules to start treatment. Take one capsule after each loose bowel movement (or as advised by your doctor).

- You can use this medicine **for up to 2 weeks** for repeated attacks, but do not take for any one attack lasting **longer than 48 hours**.
- Do not take more than **six capsules** in a 24-hour period.
- Replace lost fluid by drinking more liquid than usual.*
- Not for children and young people aged under 18.

Talk to your doctor and stop taking this medicine:

- If you have been using this medicine continuously for 48 hours.

- If you develop new IBS symptoms.
- If your IBS symptoms get worse.
- If your IBS symptoms have not improved after 2 weeks.

i How long to take IMODIUM® for IBS diarrhoea

You can use this medicine for up to 2 weeks for repeated attacks of IBS diarrhoea. But if any one attack lasts for **longer than 48 hours**, stop taking IMODIUM® and **talk to your doctor**.

Short-term diarrhoea

Age	Dose
Adults and children aged 12 and over	Take two capsules to start treatment. Take one capsule after each loose bowel movement.

- Do not take for attacks lasting **longer than 48 hours**.
- Do not take more than **six capsules** in a 24-hour period.
- Replace lost fluid by drinking more liquid than usual.*
- Not for children aged under 12.

i How long to take IMODIUM® for short-term diarrhoea

You can use this medicine for up to 48 hours. If your attack lasts longer than 48 hours, stop taking IMODIUM® and **talk to your doctor**.

If anyone takes too much of this medicine

If you have taken too many IMODIUM® IBS Relief 2mg Soft Capsules 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® IBS Relief 2mg Soft Capsules 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 you need it, 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® IBS Relief 2 mg Soft Capsules can have side effects, like all medicines, although these don't affect everyone and most are usually mild.

Get medical help at once

- Rare:** (affects less than 1 in 1,000 but 1 or more in 10,000 people)
- 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 skin.
- Loss of consciousness or reduced level of consciousness (passing out, feeling faint or less alert), muscle stiffness and uncoordinated movements.
- 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 get any of these, **stop using the medicine and get medical help at once**.

Talk to a doctor as soon as possible

- Uncommon:** (affects less than 1 in 100 but 1 or more in 1,000 people)
- Itchiness or hives.
 - Stomach pain or swollen stomach.
- Rare:** (affects less than 1 in 1,000 but 1 or more in 10,000 people)
- Difficulties passing water.
 - Severe constipation.
 - Miosis (narrowing of the pupils of the eye).
 - Hypertonia (muscle tension).
 - Coordination abnormality (uncoordinated movements).

If you notice any of the above, stop using the medicine and **talk to a doctor**.

Other effects that may occur

- Common:** (affects less than 1 in 10 but 1 or more in 100 people)
- Feeling sick, constipation or wind.
 - Headache.

- Uncommon:** (affects less than 1 in 100 but 1 or more in 1,000 people)
- Dizziness or drowsiness.
 - Vomiting, indigestion.
 - Dry mouth.

- Rare:** (affects less than 1 in 1,000 but 1 or more in 10,000 people)
- Tiredness.

Dietary soya-products are known to cause allergic reactions including severe anaphylaxis in persons with soya allergy. Patients with known allergy to peanut protein carry an enhanced risk for severe reactions to soya preparations.

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 out of the sight and reach of children.

Do not store above 25°C. Store in the original package to protect from moisture. Keep blister in the outer carton to protect from light.

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® IBS Relief 2 mg Soft Capsules is: Loperamide hydrochloride 2 mg per capsule.

Other ingredients are: Propylene glycol monocaprylate, propylene glycol, gelatin, glycerol, soya lecithin, medium chain triglycerides, brilliant blue (E133) and purified water.

What the medicine looks like

IMODIUM® IBS Relief 2 mg Soft Capsules are clear blue liquid filled capsules available in packs of 6.

Product Licence holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.

Manufacturer: Catalent France, Beinheim SA, 74 rue Principale, F-67930, Beinheim - France.

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