

Please note that there are currently 2 leaflets available for the IMODIUM INSTANT MELTS Tablets licence (PL 15513/0346).

It is the same product licence number for both leaflets i.e PL 15513/0346.

The information contained within each leaflet is identical apart from the column format and leaflet dimensions.

The leaflets are differentiated by column format (either 1 column or 5 column) as well as their respective dimensions.

1. PIL 1 (pages 2-7) - 1 column format, dimensions 145 x 250 mm
2. PIL 2 (pages 8-9) - 5 column format, dimensions 160 x 250 (x2) mm

This is a combined pdf of both leaflets.

Imodium®

Instant Melts

Loperamide hydrochloride

- This medicine is used for two different types of diarrhoea. They have **different age limits**. 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 ▶
- **If you have Irritable Bowel Syndrome (IBS)** see also Section 2 Extra warnings for IBS patients ▶
- **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® Instant Melts are used to treat **two types of diarrhoea**. The two types have different age limits.

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**.

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**.

The tablets 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

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 it is for a child aged **under 12** (or under 18 for an IBS patient).
- 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®**.

! Talk to your doctor first...

- 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 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.**
- 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® Instant Melts.

Some of the ingredients can cause problems

- This medicine contains 0.750 mg of Aspartame (E951) which is equivalent to 0.055 mg/mg. 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 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 0.00066 mg benzyl alcohol 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 liver or kidney disease, or if pregnant or breast feeding. This is because large amounts of benzyl alcohol can buildup in your body and may cause side effects (called "metabolic acidosis").
- This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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®**.

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 dose shown in the tables.
- The tablets are **not for long-term treatment**.

Short-term diarrhoea

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

- Do not take for attacks lasting **longer than 48 hours**.
- Do not take more than **six tablets** 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**.

IBS diarrhoea

Age	Dose
Adults aged 18 and over	Take two tablets to start treatment. Take one tablet 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 tablets** 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**.

If anyone takes too much of this medicine

If you have taken too many IMODIUM® Instant Melts, 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® Instant Melts 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® 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), uncoordinated movements.

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.
- Burning or prickling sensation of the tongue.
- Miosis (narrowing of the pupils of the eye).

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.

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 the sight and reach of children.

Store in the original package.

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 ingredient in IMODIUM® Instant Melts is: Loperamide hydrochloride 2 mg per tablet.

Other ingredients are: Gelatin, mannitol, aspartame, mint flavour and sodium hydrogen carbonate.

What the medicine looks like

IMODIUM® Instant Melts come in the form of white, orodispersible (dissolve in the mouth) tablets available in packs of 12 and 18 (not all pack sizes may be marketed).

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

Manufacturer:

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

This leaflet was revised July 2020.

IMODIUM® is a registered trade mark.

Imodium®

Instant Melts

Loperamide hydrochloride

■ This medicine is used for two different types of diarrhoea. They have **different age limits**. 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* ►

■ **If you have Irritable Bowel Syndrome (IBS)** see also *Section 2* Extra warnings for IBS patients ►

■ **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® Instant Melts are used to treat **two types of diarrhoea**.

The two types have different age limits.

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**.

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**.

The tablets 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

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 it is for a child aged **under 12** (or under 18 for an IBS patient).
 - 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 tablets 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 *ketconazole* (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.**
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- This medicine contains 0.750 mg of Aspartame (E951) which is equivalent to 0.055 mg/mg. 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.
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medicine will not have any noticeable effects.

- This medicine contains 0.00066 mg benzyl alcohol 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 liver or kidney disease, or if 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 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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®**.

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 dose shown in the tables.
- The tablets are **not for long-term treatment**.

Short-term diarrhoea

Age	Dose
Adults and children aged 12 and over	Take two tablets to start treatment. Take one tablet after each loose bowel movement.
<ul style="list-style-type: none"> ■ Do not take for attacks lasting longer than 48 hours. ■ Do not take more than six tablets in a 24-hour period. 	
<ul style="list-style-type: none"> ■ <i>Replace lost fluid by drinking more liquid than usual.</i> ■ 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**.

IBS diarrhoea

Age	Dose
Adults aged 18 and over	Take two tablets to start treatment. Take one tablet after each loose bowel movement (or as advised by your doctor).
<ul style="list-style-type: none"> ■ 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 tablets in a 24-hour period. 	
<ul style="list-style-type: none"> ■ <i>Replace lost fluid by drinking more liquid than usual.</i> ■ 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**.

If anyone takes too much of this medicine

If you have taken too many IMODIUM® Instant Melts, 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® Instant Melts 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® 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), uncoordinated movements.

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.
- Burning or prickling sensation of the tongue.
- Miosis (narrowing of the pupils of the eye).

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.

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.

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Keep the product out of the sight and reach of children. Store in the original package.

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

6 Further information

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The active ingredient in IMODIUM® Instant Melts is: Loperamide hydrochloride 2 mg per tablet.
Other ingredients are: Gelatin, mannitol, aspartame, mint flavour and sodium hydrogen carbonate.

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Manufacturer:

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

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