Please note that there are currently 2 leaflets available for the IMODIUM DUAL ACTION RELIEF TABLETS licence (PL 15513/0343).

It is the same product licence number for both leaflets i.e PL 15513/0343.

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

The leaflets are differentiated by manufacturer, column format (either 3 column or 2 column) as well as their respective dimensions.

1. PIL 1 (pages 2-3) - 3 column format, dimensions 160 x 536mm

Manufacturer:
Janssen-Cilag S.P.A, Via C. Janssen, Borgo San Michele, 04100 Latina, Italy.

Or

2. PIL 2 (pages 4-6) - 2 column format, dimensions 250 x 145(x2) mm

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

This is a combined pdf of both leaflets.

Both these PILs are from different manufacturer as mentioned above and it will be inserted in carton as per its manufactured site. For Latina carton, Latina PIL (PIL 1) will be inserted and for Val de Reuil site’s carton, Val de Reuil PIL (PIL 2) will be inserted.

GB - AW_160817

Imodium®

Dual Action Relief Tablets

Loperamide hydrochloride & Simeticone

- 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® Dual Action Relief 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® Dual Action Relief 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® Dual Action Relief 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® Dual Action Relief Tablets.

Important information about some of the ingredients of IMODIUM® Dual Action Relief Tablets:

- Each IMODIUM® Dual Action Relief Tablet contain less than 0.026 mg of benzyl alcohol. 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 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.
- This medicine contains less than 0.00044 mg of alcohol (ethanol) in each tablet. The small amount of alcohol in this medicine will not have any noticeable effects.
- This medicine contains maltodextrin which contains glucose. 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 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.

turn over ▸

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.

- 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® Dual Action Relief 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® Dual Action Relief 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® Dual Action Relief 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® Dual Action Relief Tablets are: Loperamide hydrochloride 2 mg and simeticone (equivalent to 125 mg dimeticone) per tablet.

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

What the medicine looks like

IMODIUM® Dual Action Relief 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 Limited, 50 -100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.

Manufacturer:
Janssen-Cilag S.P.A, Via C. Janssen, Borgo San Michele, 04100 Latina, Italy.

This leaflet was revised November 2020.

IMODIUM® is a registered trade mark.

McNeil Products Ltd.

Imodium®

Dual Action Relief Tablets

Loperamide hydrochloride & Simeticone

- 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® Dual Action Relief 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.

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 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® Dual Action Relief 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® Dual Action Relief 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® Dual Action Relief Tablets

Important information about some of the ingredients of IMODIUM® Dual Action Relief Tablets:

- Each IMODIUM® Dual Action Relief Tablet contain less than 0.026 mg of benzyl alcohol. 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 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.
- This medicine contains less than 0.00044 mg of alcohol (ethanol) in each tablet. The small amount of alcohol in this medicine will not have any noticeable effects.
- This medicine contains maltodextrin which contains glucose. 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 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.

- 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® Dual Action Relief 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® Dual Action Relief 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® Dual Action Relief 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® Dual Action Relief Tablets are:
Loperamide hydrochloride 2 mg and simeticone (equivalent to 125 mg dimeticone) per tablet.

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

What the medicine looks like

IMODIUM® Dual Action Relief 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 Limited, 50 -100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.

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

This leaflet was revised November 2020.

IMODIUM® is a registered trade mark.

McNeil Products Ltd.