June 2020

Please note that there are currently 2 leaflets available for the IMODIUM DUAL ACTION RELIEF TABLETS licence (PL 15513/0342).

It is the same product licence number for both leaflets i.e PL 15513/0342.

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

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

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

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

   or

2. PIL 2 (pages 4-7) - 2 column format, 2 colours and 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_ 160872

Imodium®

Dual Action Relief Tablets
Loperamide hydrochloride & Simeticone

Please read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. However, you still need to take IMODIUM® Dual Action Relief Tablets carefully to get the best results.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after two days.
- If any of the side-effects get serious, or if you notice any side-effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1 What the medicine is for

The tablets are used to treat a short-lived attack of diarrhoea when it occurs with stomach cramps, bloating and wind.

The tablets contain loperamide hydrochloride, which helps reduce diarrhoea by slowing down an overactive bowel. It also helps the body to absorb more water and salts from the bowel. The tablets also contain simeticone, which breaks up the 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…

- In children less **than 12 years old**.
- If you are allergic (hypersensitive) to loperamide hydrochloride, simeticone or any of the other ingredients of the tablets (see section 6).
- If you have a **high temperature** (e.g. above 38° C) or **blood in your stools**.
- If you are having a flare up of an **inflammatory bowel** condition like **ulcerative colitis**.
- If you have **severe diarrhoea** after taking antibiotics.
- If you are **constipated** or your **stomach appears swollen**.

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 **severe diarrhoea** as your body loses more fluid, sugars and salts than normal. You will need to replace the fluid by drinking more liquid than usual. Ask your pharmacist about special powders which replace the sugars and salts.
- If you have **AIDS** and your **stomach becomes swollen**, stop taking the tablets immediately and contact your doctor.
- If you have **liver disease**. Check with your doctor before using the tablets. Some of the side-effects might be more troublesome.
- 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.

Taking other medicines

Talk to your doctor or pharmacist 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)

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, because IMODIUM® Dual Action Relief Tablets may interact with them.

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.
- This medicine is not recommended if you are breast-feeding as small amounts of the medicine 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.
- 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.
- In acute diarrhoea, the symptoms usually disappear within two days. If symptoms persist after this period, stop taking this medicine and contact your doctor.

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

Do not give the tablets to children less than 12 years old.

Adults and children 12 years and over

Unless your doctor has told you otherwise, follow these instructions:

Age	Dose
Adults over 18 years old	Swallow **two tablets** initially, followed by **one tablet** after every loose stool (bowel movement).
Children and young adults (12 to 18 years)	Swallow **one tablet** initially, followed by **one tablet** after every loose stool (bowel movement).

- Do not take more than 4 tablets in a day.
- If your symptoms persist after two days, stop taking the tablets and contact 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

Take one tablet after the next loose stool (bowel movement). **Do not** take a double dose to make up for a forgotten dose.

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

4 Possible side-effects

Like all medicines, IMODIUM® Dual Action Relief Tablets can cause side-effects, although not everybody gets them.

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 and skin rash which may lead to severe blistering and peeling of the skin
- Loss of consciousness or decreased consciousness

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

- Difficulties urinating
- 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 1,000 people get these):

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

Rare side-effects (less than 1 in 1,000 but more than 1 in 10,000 people get these):

- Excessive contraction of the pupil of the eye
- 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 this medicine out of the sight and reach of children. Do not use the tablets after the expiry date on the blister and box. The expiry date refers to the last day of that month. 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.

6 Further information

What's in this medicine?

The active ingredients are: Loperamide hydrochloride (2 mg per tablet) and Simeticone (measured as 125 mg dimeticone per tablet).

The other ingredients are: Calcium hydrogen phosphate, microcrystalline cellulose, acesulfame potassium, 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

The tablets are white capsule shaped tablets marked with a line between "2" and "125" on one side and "IMO" on the other side.

Each pack contains 6, 8, 10, 12, 15, 16, 18 or 20 tablets in blister strips.

Not all pack sizes may be marketed.

Marketing Authorisation holder:
McNeil Products Ltd, 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 February 2021.

IMODIUM® is a registered trade mark.

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

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