

Package leaflet: information for the user

Imodium® Plus 2mg/125mg Tablets (loperamide hydrochloride/simeticone)

Your medicine is imported from the UK under the name of 'Imodium plus caplets' but is marketed as 'Imodium Plus 2mg/125mg Tablets' in Ireland.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Your medicine is available using the above name, but will be referred to as 'Imodium Plus' throughout this leaflet.

Always take this medicine exactly as described in this leaflet or as your pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your pharmacist.
- If you get any side effects, talk to your pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 days.

What is in this leaflet

1. What Imodium Plus is, and what it is used for.
2. What you need to know before you take Imodium Plus.
3. How to take Imodium Plus.
4. Possible side effects.
5. How to store Imodium Plus.
6. Contents of the pack and other information.

1. What Imodium Plus is, and what it is used for

The tablets contain two active ingredients:

- 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.
- Simeticone, which breaks up the gas bubbles in the bowel that causes cramps and bloating.

Imodium Plus is used in adults and adolescents aged 12 years and above, to treat a short-lived attack of diarrhoea when it occurs with stomach cramps, bloating and wind.

2. What you need to know before you take Imodium Plus

Do not take Imodium Plus:

- 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.

Warnings and precautions

Talk to your doctor or pharmacist before using Imodium Plus.

- Imodium Plus only treats the symptoms of diarrhoea. In some cases, the cause of your diarrhoea may require treatment, if symptoms persist or worsen, please contact your doctor.
- If you have severe diarrhoea 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.

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.

In acute diarrhoea, the symptoms usually disappear within two days. If symptoms persist after this period, stop taking this medicine and contact your doctor.

Children

Children under 12 years of age must not take Imodium Plus.

Other medicines and Imodium Plus

Talk to your doctor or pharmacist if you are taking, have taken or might take 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 diabetic insipidus)

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription because Imodium Plus may interact with them.

Pregnancy and breast feeding

Pregnancy: If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Breast feeding: Imodium Plus is not recommended if you are breast feeding. Small amounts of the medicine could end up in your milk.

Driving and using machines

This medicine may make you feel dizzy, tired or sleepy. If affected do not drive or operate machinery.

3. How to take Imodium Plus

Always take this medicine exactly as described in this leaflet or as your pharmacist has told you.

Check with your pharmacist if you are not sure.

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

Use in adults over 18 years old

Swallow two tablets initially, followed by one tablet after every loose stool (bowel movement). Do not take more than four tablets in a day. If your symptoms persist after two days, stop taking the tablets and contact your doctor.

Use in children and adolescents aged 12 to 18 years old

Swallow one tablet initially, followed by one tablet after every loose stool (bowel movement). Do not take more than four tablets in a day. If your symptoms persist after two days, stop taking the tablets and contact your doctor.

Use in children and adolescents less than 12 years old

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

If you take more Imodium Plus than you should

If you have taken too many Imodium Plus, 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 than adults. If a child takes too much or shows any of the above symptoms, call a doctor immediately.

If you forget to take Imodium Plus

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, this medicine 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.

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 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):

- 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971 Fax: +353 1 6762517
Website: www.hpra.ie E-mail: medsafety@hpra.ie

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

5. How to store Imodium Plus

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the carton and blister pack after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Imodium Plus contains:

The active substances are: loperamide hydrochloride (2 mg per tablet) and simeticone (measured as 125 mg dimeticone per tablet).

The other ingredients are:

calcium hydrogen phosphate anhydrous, microcrystalline cellulose, acesulfame potassium, artificial vanilla flavour (includes propylene glycol, maltodextrin and benzyl alcohol), sodium starch glycolate (Type A) and stearic acid.

What Imodium Plus looks like and contents of the pack:

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

Imodium Plus 2mg/125mg Tablets are available in blister packs of 12.

Manufacturer:

Manufactured by:
Janssen-Cilag SPA, Via C. Janssen,
Borgo San Michele, Latina, Italy.

Procured from within the EU and repackaged by:
Doncaster Pharmaceuticals Group Ltd,
Kirk Sandall, Doncaster, DN3 1QR, UK.

PPA holder:

Imbat Ltd, Unit L2, North Ring Business Park,
Santry, Dublin 9.

Distributed by:

Eurodrug Ltd, Unit L2, North Ring Business Park,
Santry, Dublin 9.

PPA1151/112/001

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium: IMODIUM® Duo 2 mg/125 mg Tabletten
Bulgaria: IMODIUM® Plus 2 mg/125 mg Caplets
Cyprus: IMODIUM® Plus
Czech Republic: IMODIUM® Plus
Denmark: IMODIUM® Plus
Finland: IMODIUM® Plus Tabletti
France: IMODIUM® duo Comprimé
Germany: IMODIUM® akut N Duo
Greece: IMODIUM® Plus
Hungary: IMODIUM® Plus 2mg/125mg tablettá
Ireland: IMODIUM® Plus 2 mg/125 mg tablet
Luxemburg: IMODIUM® Duo 2 mg/125 mg comprimés
Netherlands: IMODIUM® Duo 2 mg/125 mg, tabletten
Norway: IMODIUM® Comp
Portugal: IMODIUM® Plus
Romania: IMODIUM® Plus 2mg/125mg comprimate
Slovak Republic: IMODIUM® Plus
Spain: FORTASEC® Plus 2 mg/125 mg Comprímidos
Sweden: IMODIUM® Plus 2 mg/125 mg tablett
United Kingdom: IMODIUM® Plus caplets

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**Blind or partially sighted?
Is this leaflet hard to see or
read?**

**Call +44 (0) 1302 365000
(Regulatory)**

**Please be ready to give the
following information:
Product name: Imodium Plus
2mg/125mg Tablets
Reference No:
PPA1151/112/001**