

# Imodium<sup>®</sup> plus

2mg/125mg Chewable 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 Plus Chewable 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 Imodium Plus Chewable Tablets are, and what they are used for
2. Before you use Imodium Plus Chewable Tablets
3. How to take Imodium Plus Chewable Tablets
4. Possible side effects
5. How to store Imodium Plus Chewable Tablets
6. Further information

## 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 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.

## 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 the patient is a child 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 your doctor has told you that you have intolerances to some sugars, contact your doctor before taking this medicine.
- If any of these apply to you, **get advice from a doctor or pharmacist without taking Imodium Plus Chewable tablets.**

### **! Take special care with Imodium Plus Chewable Tablets:**

- Imodium Plus Chewable 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.
- 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.

### **! 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 (an 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)
- 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 Plus Chewable 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.
- Do not take this medicine 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.

**Important information about some of the ingredients of Imodium Plus Chewable tablets**

This medicine contains sucrose and sorbitol (E420). If your doctor has told you that you have intolerance to some sugars, contact your doctor before taking this medicine.

## 3 How to take this medicine

**Check the table overleaf to see how much medicine to take.**

- Chew the correct number of tablets.
- For oral use only.
- Do not use more than the stated dose shown in the table.

### **! Children under 12 years old**

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

turn over ▶

## **i** Adults and children 12 years and over

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

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

- Do not take more than 4 tablets in a day.
- If you are no better after two days, stop taking the tablets and contact your doctor.

### **!** If anyone takes too much of this medicine

Too many tablets may make you feel drowsy, or make it difficult to think clearly or carry out normal activities. Your muscles may feel stiff or you may experience breathing difficulties. You may have a dry mouth or the pupils of your eyes may become small. You may have stomach pain, feel sick or vomit, be constipated or have difficulty passing water. If you have taken too many Imodium Plus Chewable tablets, contact a doctor or nearest Accident and Emergency (casualty) taking this leaflet with you.

### **!** 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 Plus Chewable 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.

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, or
- 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
- 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

**If any of these side-effects becomes serious, contact a doctor or hospital immediately.**

If you notice any side-effects not listed in this leaflet, tell your **doctor** or **pharmacist** as soon as possible.

## 5 Storing this medicine

Keep out of the reach and sight 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 Simeicone (measured as 125 mg dimeicone per tablet).

The other ingredients are sucrose and corn starch, microcrystalline cellulose, basic butylated methacrylate copolymer, cellulose acetate, sorbitol (E420), dextrates, natural and artificial vanilla mint flavour (including sucrose, maltodextrin, modified corn starch, corn syrup solids, polyglycerol ester of fatty acids, calcium phosphate, enzyme modified milk powder), saccharin sodium, stearic acid and calcium phosphate

**What the medicine looks like and the contents per pack**

The chewable tablets are round, white, flat tablets with "IMO" on one side which smell of vanilla and mint. Each pack contains 2, 4, 5, 6, 8, 10, 12, 15, 16, 18 or 20 tablets in blister strips. Not all pack sizes may be marketed.

**Marketing Authorisation holder:**

McNeil Healthcare (Ireland) Limited, Airton Road, Tallaght, Dublin 24, Ireland

**Manufacturer:**

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

**This medicinal product is authorised under the following names:**

**Belgium:** Imodium Duo 2 mg/125 mg kauwtabletten

**Denmark:** Imodium Plus

**Greece:** Imodium Plus Dual Action

**Germany:** Imodium akut plus

**Luxembourg:** Imodium Duo 2 mg/125 mg kauwtabletten

**Portugal:** Imodium Plus 2 mg/125 mg comprimidos

**Spain:** Imodium Duo 2 mg/125 mg Chewable Tablets

**This leaflet was revised July 2012**

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11/0179  
IE - AW\_69930

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INSERT IMODIUM PLUS

Market: IE

**Article Number: AW\_69930**

Mat. ID Code: NA

Format Name: I/004/V2 (150x300)

Operator: Deepak

Technical Info/Spec: NA

Pointsize: 7 pt

File Name: AW\_69930.indd (CS4\_PC)

L A B

■ Black

■ PMS 320

■ PMS 258

Date: 1. 17-06-2011

2. 17-06-2011

3. 06-07-2012 (Prabhu)

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