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**This amendment:** Response to Clinical Recommendation.

**Date of original submission:** 12 December 2016

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## IMODIUM® 2 mg

### PATIENT INFORMATION LEAFLET

#### SCHEDULING STATUS

S2

#### IMODIUM® 2 mg tablets

Loperamide hydrochloride.

Contains sugar: Each tablet contains 75 mg lactose monohydrate.

**Read all of this leaflet carefully because it contains important information for you.**


IMODIUM® 2 mg is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to take IMODIUM® 2 mg carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share IMODIUM® 2 mg with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve (after 48 hours).

#### What is in this leaflet

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

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## 1. What IMODIUM® 2 mg is and what it is used for

IMODIUM® 2 mg is used to treat diarrhoea in adults and children 6 years and older.

It contains 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 your body.

In children under the age of 6 years IMODIUM® 2 mg is used to slow down an overactive bowel.

IMODIUM® 2 mg is not indicated for use in children under the age of 2 years and is not suitable for use in children under 6 years of age. It should only be given to children under the age of 6 years with a prescription and under the supervision of a doctor.

## 2. What you need to know before you take IMODIUM® 2 mg

### Do not take IMODIUM® 2 mg:


- if you or your child are hypersensitive (allergic) to loperamide hydrochloride or any of the other ingredients of IMODIUM® 2 mg (see **What IMODIUM® 2 mg contains**);
- if you or your child have acute dysentery (symptoms may include blood in your stools and fever);
- if you have a flare-up of an inflammatory bowel condition like ulcerative colitis or if you have inflammation of your bowels caused by bacterial infections;
- if you or your child have severe diarrhoea after taking antibiotics;
- if you or your child are constipated, or your stomach appears swollen (especially in children with severe dehydration).

IMODIUM® 2 mg is contraindicated for use in children under the age of 2 years.

### Warnings and precautions

Take special care with IMODIUM® 2 mg:

- if you or your child have severe diarrhoea as your body loses more fluid, sugars and salts

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than normal. IMODIUM® 2 mg should only be given to children under the age of 6 years with a prescription and under the supervision of a doctor;

- if you or your child have diarrhoea that lasts for more than 48 hours;
- if you or your child have acquired immunodeficiency syndrome (AIDS) and your stomach becomes swollen, stop taking IMODIUM® 2 mg immediately and contact your doctor;
- if you or your child suffer from any liver disease;
- if you have a history of substance abuse.

### **Children and adolescents**

IMODIUM® 2 mg is contraindicated for use in children under the age of 2 years and is not suitable for use in children under 6 years of age. It should only be given to children under the age of 6 years with a prescription and under the supervision of a doctor.


### **Other medicines and IMODIUM® 2 mg**

Always tell your health care provider if you or your child are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you or your child are currently using:

- quinidine (used to treat malaria);
- ritonavir (used to treat HIV/AIDS);
- itraconazole or ketoconazole (used to treat fungal infections);
- gemfibrozil (used to treat cholesterol (high levels of fat in your blood));
- desmopressin (used to control increased thirst and too much urination);
- any other medicines used to treat diarrhoea.

### **IMODIUM® 2 mg with food, drink and alcohol**

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See section 3.

### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking IMODIUM® 2 mg.

The safety of IMODIUM® 2 mg during pregnancy has not been established. Small amounts of IMODIUM® 2 mg is excreted in breast milk.

Do not use IMODIUM® 2 mg if you are pregnant or breastfeeding your baby.

### **Driving and using machines**

You may experience tiredness, dizziness or drowsiness if you suffer from diarrhoea and you are taking IMODIUM® 2 mg. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how IMODIUM® 2 mg affects you.

### **IMODIUM® 2 mg contains lactose**


If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking IMODIUM® 2 mg.

### **3. How to take IMODIUM® 2 mg**

Do not share medicines with any other person.

**IMODIUM® 2 mg is contraindicated in children under the age of 2 years. The tablets are not suited for children under 6 years of age and should only be given to children under the age of 6 years under medical prescription or supervision.**

*Short-term diarrhoea:*

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Adults:

The usual dose is 2 tablets as an initial dose, followed by 1 tablet after each subsequent loose stool.

Children (older than 6 years):

The usual dose is 1 tablet as an initial dose followed by 1 tablet after each subsequent loose stool.

Do not exceed the following maximum daily dosages:


WEIGHT IN KILOGRAMS (kg)	MAXIMUM DAILY DOSE
From 14 kg	2 tablets (4 mg)
From 20 kg	3 tablets (6 mg)
From 27 kg	4 tablets (8 mg)
From 34 kg	5 tablets (10 mg)
From 40 kg	6 tablets (12 mg)
From 47 kg	7 tablets (14 mg)
From 54 kg	8 tablets (16 mg)

Always take IMODIUM® 2 mg exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

It is important that you stop taking IMODIUM® 2 mg as soon as your or your child's diarrhoea is under control.

Do not take for attacks that last longer than 48 hours. If your diarrhoea does not get better, you must contact your doctor.

*Long-lasting diarrhoea (as per consultation with your doctor)*

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Adults:

The usual dose is 2 tablets daily.

Children (older than 6 years):

The usual dose is 1 tablet daily.

*Instructions for use:*

Swallow the tablets with a drink of water.

If you have the impression that the effect of IMODIUM® 2 mg is too strong or too weak, tell your doctor or pharmacist.

#### **If you take more IMODIUM® 2 mg than you should**

In the event of an overdose, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.


Take this leaflet and the rest of the remaining IMODIUM® 2 mg with you so the doctor will know what you have taken.

#### **If you forget to take IMODIUM® 2 mg**

You should only take IMODIUM® 2 mg as you need it. If you forget to take a dose, take your next dose after your next loose stool. Do not take a double dose to make up for forgotten individual doses.

#### **4. Possible side effects**

IMODIUM® 2 mg can have side effects.

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Not all side effects reported for IMODIUM® 2 mg are included in this leaflet. Should your or your child's general health worsen or if you or your child experience any untoward effects while taking IMODIUM® 2 mg, please consult your health care provider for advice.

If any of the following happens, stop taking or giving IMODIUM® 2 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you or your child may have had a serious allergic reaction to IMODIUM® 2 mg. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

*Side effects occurring less frequently:*


- lack of bowel movements causing severe constipation;
- severe stomach pain or swelling;
- severe, painful skin rash causing blistering or peeling of the skin, also known as Stevens-Johnson syndrome, toxic epidermal necrolysis or erythema multiforme;
- difficulty urinating.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

*Side effects occurring frequently:*

- headache;

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- dizziness;
- constipation, dry mouth, flatulence (excessive wind), cramping or pain in your stomach area, nausea (feeling sick), vomiting (being sick), colic.

*Side effects occurring less frequently:*

- swelling or discomfort of your stomach area, indigestion;
- drowsiness;
- abnormal coordination, stiffness (difficulty moving);
- reduced level of consciousness or loss of consciousness (passing out, feeling faint or less alert);
- constriction of your pupils;
- tiredness.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.


### **Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications: <http://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of IMODIUM® 2 mg.

For further information, please contact the Johnson and Johnson call centre on 0860 410032 (landline).

### **5. How to store IMODIUM® 2 mg**

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- Store at or below 25 °C.
- Protect from light.
- Keep in the original container until required for use.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

### What IMODIUM® 2 mg contains

Each tablet contains 2 mg loperamide hydrochloride.

The other ingredients are corn starch, lactose monohydrate, microcrystalline cellulose (E460(i)), modified starch, vegetable oil.

### What IMODIUM® 2 mg looks like and contents of the pack

Round, white, odourless, biconvex tablet engraved "JANSSEN" on the one side and "1/2" on the reverse side.

Carton with one aluminium blister of 6 tablets.

### Holder of certificate of registration


Johnson & Johnson (Pty) Ltd.

241 Main Road

Retreat

7945

South Africa

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**This leaflet was last revised in**

Date of registration: 04 March 2005

Date of revision: 10 March 2022

**Registration number**

H/11.9/152

**Access to the corresponding Professional Information**

The latest electronic Professional Information may be found at the SAHPRA website:

<https://www.sahpra.org.za/pi-pil-repository/>.

Alternatively, you may directly contact Johnson & Johnson (Pty) Ltd.:

Consumer Contact Centre:

0860 410032 (South Africa Only)

SMS jnj & comment to +27 83 293 3273

Email: [jnjza@its.jnj.com](mailto:jnjza@its.jnj.com)

**EXPORT REGISTRATION DETAILS:**

Botswana: B9315240

Namibia: NS1 90/11.9/00625

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