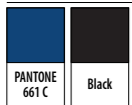


Project Name / Design	IE_Imodium LiqueRelief Soft Caps 12_PIL_CRD XXXX		
New Component / Item Code	386795	ArtWorks ID	EMEA_2022_00067410_001
Old Component / Item Code	376317	Languages	English
Product / Eurocode / Mat. ID Code	7088110	Job / Version No.	402974713_r1
		Date	25-10-2022



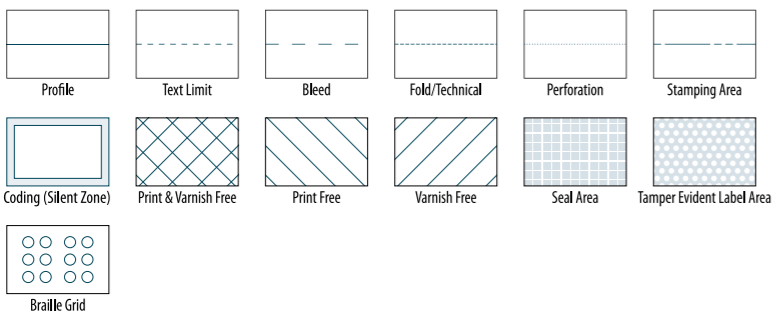
REPRESENTATION:  Colours represented with a diagonal line have been modified to aid PDF approval.

**MANUFACTURING SITE**

Reference	3P_CAT-GER/I/140x300/V1	Security Code / ICFP	9997
Substrate	WHITE		

**TECHNICAL DETAILS**

Component	Leaflet	Plant	Catalent Germany
Dimensions	140 x 300 mm	Master Dieline	JJEXT_00143_V1
		Date	26-11-2020



<b>Fonts used</b>	HelveticaWorld-Bold	<b>Smallest Text Size</b>
	HelveticaWorld-Italic	6.0pt
	HelveticaWorld-Regular	<b>Ave. Text Size</b>
		7.0pt
		<b>Largest Text Size</b>
		10.5pt

# Imodium®

## LiquiRelief 2mg soft Capsules

Loperamide hydrochloride

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

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

- This medicine is used to treat the sudden short-lived (acute) attacks of diarrhoea in 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.** These are shown in the dosage tables. See Section 3

**Now read this whole leaflet carefully before you use this medicine.**

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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 24 hours.

**What is in this leaflet**

1. What IMODIUM® LiquiRelief Capsules are, and what they are used for.
2. What you need to know before you take IMODIUM® LiquiRelief Capsules.
3. How to take IMODIUM® LiquiRelief Capsules.



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4. Possible side effects.
5. How to store IMODIUM® LiquiRelief Capsules.
6. Contents of the pack and other information.

### 1 What IMODIUM® LiquiRelief Capsules are and what they are used for

IMODIUM® LiquiRelief Capsules is a medicine which is used to treat sudden short-lived (acute) attacks of diarrhoea in adults and children aged 12 years and over. The capsules contain loperamide hydrochloride which helps reduce diarrhoea by slowing down an overactive bowel to its normal rhythm, which helps the body to absorb water and salts from the bowel.

### 2 What you need to know before you take IMODIUM® LiquiRelief Capsules

This medicine is suitable for most people, but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

**Do not take IMODIUM® LiquiRelief Capsules:**

- 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 (particularly in children with severe dehydration).
- If you have acute dysentery, the symptoms of which may include blood in your stools and a high temperature.
- If you are allergic to opium or soya lecithin, as this product contains trace amounts of soya lecithin.

If any of these apply to you, get advice from a doctor or pharmacist without taking IMODIUM® LiquiRelief Capsules.

**Warnings and Precautions**

- Talk to your doctor or pharmacist before using IMODIUM® LiquiRelief Capsules if you have AIDS and your stomach becomes swollen, stop taking the medicine immediately and contact your doctor.
- If you suffer from liver disease.
- If your diarrhoea lasts for more than 24 hours.



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- If you have severe diarrhoea as your body loses more fluid, sugars and salts than normal.
- 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® LiquiRelief Capsules.

**Other medicines and IMODIUM® LiquiRelief Capsules**

- If you are taking any other medicines, including:
  - rifonaxiv (used to treat HIV) or quinidine (used to treat abnormal heart rhythms or malaria),
  - itraconazole or ketoconazole (antifungal medicines)
  - gemfibrozil (used to treat high cholesterol)
  - oral desmopressin (used to control thirst and urine production in patients with diabetic insipidus)

If any of these bullet points apply to you now or in the past, talk to a doctor or pharmacist. If you are unsure about any of the medicines you are taking, show the bottle or pack to your pharmacist.

**Pregnancy and breast-feeding**

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

**Driving and using machines**

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

**Other information about this medicine**

- IMODIUM® LiquiRelief Capsules only treat the symptoms of diarrhoea. 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. The prevention of fluid depletion (dehydration) is of particular importance in infants, children and frail and elderly people with acute diarrhoea.



### **A** Some of the ingredients can cause problems

- This medicine contains 115.31 mg propylene glycol in each capsule which is equivalent to 0.65 mg/mg.
- This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

### 3 How to take IMODIUM® LiquiRelief Capsules

Check the tables below to see how much medicine to take.

- Swallow the correct number of capsules whole with a drink of water.
- For oral use only.
- Do not use more than the stated dose shown in the tables.

#### **i** Children under 12 years old

This medicine is not recommended for children under 12 years old.

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

To treat sudden short-lived (acute) diarrhoea:

Age	Dose
Adults and children aged 12 years and over	Swallow <b>2 capsules</b> initially, followed if required, by <b>1 capsule</b> after every further loose bowel movement.
	<ul style="list-style-type: none"> <li>■ Do not take more than 5 capsules in any 24 hour period.</li> <li>■ If symptoms persist for more than 24 hours talk to your doctor.</li> </ul>

### **A** If you take more IMODIUM® LiquiRelief Capsules than you should

If you have taken too many IMODIUM® LiquiRelief Capsules, 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, or weak breathing. Children react more strongly to large amounts of IMODIUM® LiquiRelief Capsules than adults. If a child takes too much or shows any of the above symptoms, call a doctor immediately.



### 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 HPRRA Pharmacovigilance, website: [www.hpra.ie](http://www.hpra.ie).

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

### 5 How to store IMODIUM® LiquiRelief Capsules

Keep the product out of the reach and sight of children. Do not store above 25°C.

Store in the original package in order to protect from moisture and light.

Do not use your medicine after the date shown as the expiry date (EXP) on the packaging. The expiry date refers to the last day of the month.

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® LiquiRelief Capsules contains

**The active ingredient in IMODIUM® LiquiRelief is Loperamide hydrochloride.** Each soft capsule contains 2 mg Loperamide hydrochloride.

**Other ingredients are: Capsule fill:** Propylene glycol monooxylate, Propylene glycol (E1520), Purified water. **Capsule shell:** Gelatin, Glycerol 99% (E422), Propylene glycol (E1520), FD&C Blue (E133), Soya lecithin (E322) and Triglycerides, medium chain.

#### What IMODIUM® LiquiRelief Capsules looks like and contents of the pack

IMODIUM® LiquiRelief Capsules are clear blue liquid filled capsules available in packs of 12.

#### Marketing Authorisation holder:

Johnson & Johnson (Ireland) Limited, Airtown Road, Tallaght, Dublin 24, Ireland.

#### Manufacturer:

Catalent France, Beinheim SA, 74 rue Principale, F-67930 Beinheim - France.

This leaflet was revised October 2022.

IMODIUM® is a registered trade mark.

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