Imodium 2 mg Capsules

Loperamide Hydrochloride

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

- IMODIUM® 2mg Capsules is used to treat sudden, shortlived (acute) attacks of diarrhoea in adults and children 4 years and over and long-lasting (chronic) diarrhoea in adults.
- **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 are allergic to loperamide or any of the other ingredients of this medicine. *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 table. *See Section 3* ▶

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for **you only. Do not pass it on to others.** It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. *See Section 4* ▶

What is in this leaflet

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

1 What IMODIUM® 2mg Capsules are and what they are used for

IMODIUM® 2mg Capsules is used to treat sudden, shortlived (acute) attacks of diarrhoea in adults and children 4 years and over and long-lasting (chronic) diarrhoea in adults, such as diarrhoea associated with Crohn's disease and ulcerative colitis (conditions in which the bowels become inflammed). The capsules contain loperamide hydrochloride which helps reduce diarrhoea by slowing down an overactive bowel, which helps the body to absorb water and salts from the bowel.

2 What you need to know before you take IMODIUM® 2mg 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® 2mg Capsules:

- If you are allergic to loperamide or any of the other ingredients of this medicine (listed in section 6).
- If it is for a child **under 4 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 have had a **bacterial infection** of the small intestine or colon.
- If you have a **blockage of the bowel**, including a blockage due to paralysis of the bowel wall.
- If you have an **enlargement of the colon**, particularly if this enlargement is very rapid.

If any of these apply to you, **get advice from a doctor or pharmacist without taking IMODIUM® 2mg Capsules.**

Warnings and Precautions

Talk to your doctor or pharmacist before using IMODIUM® 2mg Capsules.

- IMODIUM® 2mg Capsules only treats the symptoms of diarrhoea. Whenever the cause can be identified, it should be treated appropriately.
- Please talk to your doctor or pharmacist if:
- 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 more than 24 hours, please consult your doctor.
- 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® 2mg Capsules.

Other medicines and IMODIUM® 2mg Capsules

- If you are taking any other medicines because taking some medicines together can be harmful. You should not take any other antidiarrhoeal medicines whilst taking IMODIUM® 2mg Capsules (except for oral rehydration therapy).
- If you are taking any **other medicine**, including:
  - *ritonavir* (used to treat HIV) or *quinidine* (used to treat **abnormal heart rhythms** or **malaria**).
  - *itraconazole* or *ketaconazole* (**antifungal** medicines)
  - *gemfibrozil* (used to treat **high cholesterol**)
  - *oral desmopressin* (used to **control thirst** and **urine production** in patients with diabetic insipidus)

If you are unsure about any of the medicines you are taking, show the bottle or pack to your pharmacist.

If any of these bullet points apply to you now or in the past, **talk to a doctor or 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® 2mg Capsules only treats 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.

Some of the ingredients can cause problems

- This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3 How to take IMODIUM® 2mg Capsules

- Swallow the correct number of capsules whole with some liquid.
- Adults should supervise young children taking this product, in order to avoid any potential risk of choking.
- Do not give to children under 4 years of age.

How much should you take?

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your pharmacist if you are not sure.
The dose of IMODIUM® 2mg Capsules that you will need will depend on whether your diarrhoea is a sudden, short-lived attack (acute) or a long-lasting condition (chronic).

If symptoms persist or get worse, or if new symptoms occur, stop use and talk to your doctor.

Acute diarrhoea

Adults and Children aged 9-12 years:
Take one or two capsules to begin with and then one capsule three times daily. Never take more than 5 capsules in any 24 hour period.

Children aged 4-8 years:
Take a maximum of 4mg (2 capsules) daily in divided doses.
If your symptoms are not getting better within 2 days of taking your first dose of IMODIUM® 2mg Capsules, you should see your doctor again. The reason is that your doctor may want to examine you to further check on the cause of the diarrhoea.

Use in the elderly, patients with kidney or liver problems

No dose adjustment is required for the **elderly** or patients with **kidney** problems. However, if you have **liver** problems you should speak to your doctor or pharmacist before taking this medicine.

Chronic diarrhoea

Adults **only**:
Your doctor will tell you how much IMODIUM® 2mg Capsules to take. The initial dose will probably be between two and four capsules per day taken in divided doses. Never take more than 5 capsules in any 24 hour period.
The dose given will depend on each individual's needs. When your doctor is satisfied that you are receiving the daily dose that best suits you, he or she will probably suggest that the frequency at which you take IMODIUM® is twice a day.

If you take more IMODIUM® 2mg Capsules than you should

If you have taken too many IMODIUM® 2mg 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, partial unconsciousness, the pupils of your eyes may become small, stomach pain, bloating, constipation, difficulty urinating, or weak breathing.
Children react more strongly to large amounts of IMODIUM® 2mg Capsules 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® 2mg Capsules

You should only take this medicine as required following the dosage instructions above carefully. If you forget to take a dose, take a dose after the next loose stool (bowel movement). **Do not** take a double dose.

4 Possible side effects

Like all medicines, IMODIUM® 2mg Capsules 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 unexplained wheezing, shortness of breath, passing out or swelling of face and throat.
- Skin rashes which may be severe and include blistering or peeling of the skin.
- Loss of consciousness or reduced level of consciousness.
- Not known (frequency cannot be estimated from the available data): Upper abdominal pain, abdominal pain that radiates to back, tenderness when touching the abdomen, fever, rapid pulse, nausea, vomiting, which may be symptoms of inflammation of the pancreas (acute pancreatitis).

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

Common: may affect up to 1 in 10 people.
- Headache
- Constipation
- Nausea
- Flatulence

Uncommon: may affect up to 1 in 100 people.
- Dizziness or drowsiness
- Feeling sick, vomiting or indigestion
- Tiredness
- Dry mouth
- Stomach discomfort
- Rash

Rare: less than 1 in 1,000 people are affected.

- Itchiness or hives
- Difficulties passing water
- Stomach pain or swollen stomach
- Severe constipation
- Hypertonia (muscle tension)
- Coordination abnormality (uncoordinated movements)
- Miosis (constriction of the eye pupil)
- Ileus (blockage of the bowel, this may be due to paralysis of the bowel wall)
- Megacolon (enlargement of the colon, this may be rapid)

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, website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store IMODIUM® 2mg Capsules

Keep out of the sight and reach of children. There are no special storage precautions for the capsules. Do not use the medicine after the expiry date printed on the outer carton and on the blister packaging. The expiry date refers to the last day of that 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® 2mg Capsules contains

The active ingredient in IMODIUM® 2mg Capsules is Loperamide hydrochloride. Each capsule contains 2mg loperamide hydrochloride.
Other ingredients in the capsules are: lactose*, maize starch, talc and magnesium stearate.

The capsule itself is made up of titanium dioxide (E171), yellow ferric oxide and black ferric oxide (E172), indigotindisulphonate sodium (E132), erythrosine (E127) and gelatin.
* If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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

IMODIUM® 2mg Capsules are available to the pharmacist in packs of 60 capsules. Each capsule consists of a gelatin outer shell with an opaque green cap and an opaque dark grey body, containing white powder.

Marketing Authorisation holder:
JNTL Consumer Health I (Ireland) Ltd.
Block 5, High Street, Tallaght, Dublin 24, Ireland.

IMODIUM® 2mg Capsules are manufactured by JNTL Consumer Health (France) SAS,
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