PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

IMODIUM® CAPS

2 mg Loperamide hydrochloride per capsule

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

IMODIUM CAPS is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use IMODIUM CAPS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share IMODIUM CAPS with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 2 days.
- In sudden (acute) diarrhoea, if clinical improvement is not observed within 48 hours, the administration of IMODIUM CAPS should be discontinued and you should consult your doctor.

1. WHAT IMODIUM CAPS CONTAINS

- The active substance is loperamide hydrochloride. Each capsule contains 2 milligrams of loperamide hydrochloride.
- The other ingredients are:

Lactose monohydrate, magnesium stearate, maize starch, and talc. The capsule itself is made from yellow ferric oxide, indigotindisulphonate sodium, black ferrous oxide, erythrosine sodium, titanium dioxide and gelatine.

Contains sugar (lactose).

2. WHAT IMODIUM CAPS ARE USED FOR

It is used to treat sudden diarrhoea or chronic diarrhoea. If the diarrhoea persists, consult your doctor.

3. BEFORE YOU TAKE IMODIUM CAPS:

Do not use IMODIUM CAPS:

- If you are hypersensitive **(allergic)** to loperamide hydrochloride or any of the other ingredients of IMODIUM CAPS. (Refer to WHAT IMODIUM CAPS CONTAINS, above),
- **Do not give IMODIUM CAPS to children under 6 years.**
- If there is **blood in the stools** or you have **a high temperature**.
- If you have an **inflammation of the lower bowel** (for example, ulcerative colitis or pseudomembranous colitis as a result of using antibiotics).
- If your doctor has told you that you have a condition where slowing of the intestine should be avoided. For example, if you are **constipated** or your **abdomen** is **swollen**.

If in doubt, ask your pharmacist or doctor for advice.

Take special care with IMODIUM CAPS:

- IMODIUM CAPS will not treat the cause of diarrhoea. When you have diarrhoea, you will lose a lot of fluids. You should therefore replace lost fluids by taking much more liquids than you normally would. Special rehydration fluids may be needed**.** This is especially important for children.

- Tell your doctor if you have **liver problems**, the doctor will decide if you can take IMODIUM CAPS.
- If you have HIV/AIDS and are being treated with IMODIUM CAPS for diarrhoea, and if you have any signs of abdominal swelling or bulging, stop taking IMODIUM CAPS immediately and tell your doctor.
- Abuse and misuse of loperamide, the active ingredient in IMODIUM CAPS, have been reported. Do not take this product for anything other than its intended use and never take more than the recommended amount.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

You should not use IMODIUM CAPS if you are pregnant.

You are advised not to take IMODIUM CAPS if you are breastfeeding **your infant because** the active ingredient of IMODIUM CAPS can be transferred into your breastmilk.

Driving and using machinery:

IMODIUM CAPS can cause dizziness, therefore it is advisable to use caution when driving a car or operating machinery.

Important information about some of the ingredients of IMODIUM CAPS

IMODIUM CAPS contain lactose, which may have an effect on the glycaemic control of patients with diabetes mellitus. Patients with rare hereditary problems of galactose

intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Taking other medicines with IMODIUM CAPS:

Always tell your healthcare professional if you are taking any other medicine (This includes complementary or traditional medicine).

In particular, tell your doctor or pharmacist if you are taking any of the following:

- Ritonavir (used to treat HIV),
- Quinidine (used to treat abnormal heart rhythms),
- Oral desmopressin (used to treat excessive urination),
- Itraconazole or ketoconazole (used to treat fungal infections),
- Gemfibrozil (used to lower cholesterol).

4. HOW TO TAKE IMODIUM CAPS:

The dose of IMODIUM CAPS that you will need to take will depend on your age and the type of **diarrhoea.**

IMODIUM CAPS are to be taken by the mouth. The capsules should be taken with liquid.

You can take IMODIUM CAPS at any time of day.

Do not share IMODIUM CAPS prescribed for you with any other person.

Adults (including elderly)

- for sudden (acute) **diarrhoea**, take 2 capsules at once, then take 1 capsule after every loose stool. If you have a solid or hard stool, or if you go for 24 hours without a bowel movement, do not take any more capsules.

- for chronic diarrhoea, the right dose should be prescribed by your doctor.

But: **Do not take more than 8 capsules in any 24 hour period.**

Children aged 6 years and over

- for sudden (acute) diarrhoea, take 1 capsule to begin with, then 1 capsule after each loose stool. If the child has a solid or hard stool or goes for 24 hours without a bowel movement, do not give any more capsules.
- for long-lasting (chronic) diarrhoea, the right dose should be worked out in consultation with your doctor.

Never give more than the maximum recommended dose per day and per kilogram of your child's weight.

Child's weight in kilograms (kg)	**Maximum number of IMODIUM capsules per day**
from 27 kg	Never more than 4
from 34 kg	Never more than 5
from 40 kg	Never more than 6
from 47 kg	Never more than 7
from 54 kg	Never more than 8

If in doubt, ask your doctor or pharmacist for **advice**.

If you take more IMODIUM CAPS than you should:

If you have taken too much IMODIUM CAPS, immediately contact a doctor or a hospital for advice, if you have any of the following symptoms: increased heart rate, irregular heartbeat, changes to your heartbeat, (these symptoms can have potentially serious, life threatening consequences), muscle stiffness, unco-ordinated movements, drowsiness, difficulty urinating or weak breathing.

Children react more strongly to large amounts of IMODIUM CAPS than adults. If a child takes too much or shows any of the above symptoms, call a doctor immediately.
In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

5. POSSIBLE SIDE EFFECTS

IMODIUM CAPS can have side effects.

Not all side effects reported for IMODIUM CAPS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking IMODIUM CAPS, please consult your doctor, pharmacist or other healthcare professional for advice.

Stop using IMODIUM CAPS and tell your doctor straight away if you notice or suspect any of the following. You may need urgent medical treatment.

- Sudden swelling of the face, lips or throat, difficulty in swallowing, shortening of breath, hives (also known as nettle rash or urticaria), severe irritation, reddening or blistering of your skin. These may be signs of a severe hypersensitivity or allergic reaction.
- Extreme tiredness, being unable to move in a coordinated way, loss of consciousness.
- Severe stomach pain, stomach bulging or swelling or fever which may be due to a blocked or enlarged bowel.

Tell your doctor if you notice any of the following side effects while using IMODIUM CAPS:

- Dry mouth, dyspepsia (indigestion), stomach pain, discomfort or distension (bloating), nausea (feeling sick), vomiting (being sick), flatulence (wind), constipation,
- Headache, dizziness, tiredness, feeling sleepy and feeling weak,
- Rash,

- Urinary retention (difficulty urinating or passing water),
- Miosis (narrowing of the eye pupils).

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

6. STORING AND DISPOSING OF IMODIUM CAPS

Keep IMODIUM CAPS capsules at or below 25 °C. This medicine can be kept for only a limited period. Do not use IMODIUM CAPS after the date (month and year) mentioned after "EXP", even if it has been stored properly. You are advised to return expired medicine to your pharmacist.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Store all medicines out of the reach of children.

7. PRESENTATION OF IMODIUM CAPS

Carton containing one or more blister strips of 6 capsules each.

8. IDENTIFICATION OF IMODIUM CAPS

IMODIUM capsules are grey and green.

9. REGISTRATION NUMBER

U/11.9/213

10. THE NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

JANSSEN PHARMACEUTICA (Pty) Ltd

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11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

Date on registration certificate: 08 April 1988

Most recently revised patient information leaflet as approved by the Advisory Clinical Committee:

27 January 2020