PACKAGE LEAFLET: INFORMATION FOR THE USER

IMODIUM® ORIGINAL Hard 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 or nurse has told you.

- 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 doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to your doctor if you do not feel better or if you feel worse after 2 days.

What is in this leaflet

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

1 What IMODIUM® ORIGINAL is and what it is used for

The name of your medicine is IMODIUM® ORIGINAL capsules.

What IMODIUM® ORIGINAL is used for
IMODIUM® ORIGINAL is used:

- To treat sudden short-lived (acute) attacks of diarrhea in adults and children age 12 and over.

If your child is aged 12 years and above the 'you' stated everywhere below should be read as 'your child'.

How IMODIUM® ORIGINAL works
IMODIUM® ORIGINAL contain a medicine called loperamide hydrochloride. It belongs to a group of medicines which helps reduce diarrhoea by slowing down an overactive bowel. It also helps the body to absorb more water and salts from the bowel.

2 What you need to know before you take IMODIUM® ORIGINAL

Do not take IMODIUM® ORIGINAL if:

- You are allergic to anything in IMODIUM® ORIGINAL (listed in section 6 below)
- You have severe diarrhea after taking antibiotics

- You are having a flare up of ulcerative colitis
- You are constipated or your stomach appears swollen
- For a child less than 12 years old
- If you have acute dysentery, the symptoms of which may include blood in your stools and a high temperature. You will also need to be given other medicines to treat this

Do not use this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before using IMODIUM® ORIGINAL.

Warnings and precautions
Talk to your doctor or pharmacist or nurse before taking IMODIUM® ORIGINAL if:
- You suffer from liver problems
- You have AIDS and your stomach becomes swollen. Stop taking IMODIUM® ORIGINAL immediately and contact your doctor
- You have diarrhea that lasts for more than 48 hours.
- You have been told by your doctor that you have an intolerance to some sugars

You may still be able to take IMODIUM® ORIGINAL, but you should discuss this with your doctor first.

Replacing fluid and salts
IMODIUM® ORIGINAL only treat the symptoms of diarrhea. When you have diarrhea, your body loses large amounts of fluid and salts. You should therefore replace this lost fluid by drinking more than normal. This is especially important for children, frail and older people.

Your doctor may also give you a special powder containing sugar and salts (known as oral rehydration therapy) to help your body replace the fluid and salts lost during diarrhea.

Other medicines and IMODIUM® ORIGINAL
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription or herbal medicines. If you are unsure about any of the medicines you are taking, show the bottle or pack to your pharmacist.

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 or malaria)
- Itraconazole, ketoconazole (used to treat fungal infections)
- Gemfibrozil (used to reduce levels of cholesterol)
- Oral desmopressin (used to treat excessive urination)
- Other drugs that slow down or speed up movement in the gut

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby.

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Do not take this medicine if you are breastfeeding 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. You may also lose consciousness, feel faint or less alert. If affected do not drive or operate machinery.

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® ORIGINAL.

Important information about some of the ingredients of IMODIUM® ORIGINAL
IMODIUM® ORIGINAL contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3 How to take IMODIUM® ORIGINAL

Always take IMODIUM® ORIGINAL exactly as prescribed in this leaflet or as your doctor, or pharmacist, or nurse has told you. You should check with your doctor, or pharmacist, or nurse if you are not sure.

Taking this medicine
- Take this medicine by mouth.
- Swallow the correct number of capsules whole with a drink of water.

How much to take

Adults and children over 12 years old
- Take 2 capsules straight away
- From then on take 1 capsule after each episode of diarrhea
- You can take this medicine for up to 2 days
- Never take more than 6 capsules in any 24hour period

Replace lost fluid by drinking more liquid than usual.

If you are not getting better within 2 days of taking your first dose of IMODIUM® ORIGINAL, go back to your doctor. He or she may want to examine you to check on why you have diarrhea.

Children
There is limited data available regarding use in children below 12 years of age. Please refer to Section 4-Possible side effects.

If you forget to take IMODIUM® ORIGINAL
- 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 to make up for a forgotten dose

If you take more IMODIUM® ORIGINAL than you should
If you have taken too many IMODIUM® ORIGINAL, 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® ORIGINAL than adults. If a child takes too much or shows any of the above symptoms, call a doctor immediately.

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® ORIGINAL can cause side effects, although not everybody gets them.

Stop taking IMODIUM® ORIGINAL 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. Hives (also known as nettle rash or urticaria), severe irritation, reddening or blistering of your skin. These may be signs of a severe allergic reaction
- Blistering of your skin, mouth, eyes and genitals
- Stomach pain or severe swollen stomach
- Severe constipation
- Loss of consciousness or reduced level of consciousness (feeling faint or less alert)

  Not known (frequency cannot be estimated from the available data)
  Upper abdominal pain, abdominal pain that radiates to back, tenderness when touching theabdomen, fever, rapid pulse, nausea, vomiting, which may be symptoms of inflammation ofthe pancreas (acute pancreatitis).

Tell your doctor if you notice any of the following side effects while taking IMODIUM® ORIGINAL:

Common side effects (affects more than 1 in 100 patients)
- Headache
- Feeling dizzy
- Feeling sick (nausea)
- Constipation
- Wind

Uncommon side effects (affects fewer than 1 in 100 patients)
- Feeling sleepy or drowsy
- Dry mouth
- Being sick (vomiting), indigestion (dyspepsia)
- Rash

Rare side effects (affects less than 1 in 1000 patients)

- Tiny pupils
- Itchy skin
- Difficulty passing water
- Feeling tired
- Problems with coordination
- Unusually stiff muscles causing poor control of movement

Some of the listed side effects may be due to the diarrhea, such as discomfort around the middle, feeling sick or being sick, dry mouth, feeling tired, drowsy or dizzy and gases.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist or nurce. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

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

5 How to store IMODIUM® ORIGINAL

Keep this medicine out of the sight and reach of children.

Do not use IMODIUM® ORIGINAL after the expiry date which is stated on the blister and the label. The expiry date refers to the last day of that month.

Store below 25°C.

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® ORIGINAL contains
- **The active substance** in IMODIUM® ORIGINAL hard capsules is loperamide hydrochloride. Each IMODIUM® ORIGINAL hard capsule contains 2 mg of loperamide hydrochloride.
- **The other ingredients** are lactose, maize starch, talc and magnesium stearate (E572). The hard capsule itself is made up of titanium dioxide (E171), iron oxides (E172), indigo carmine (E132), erythrosine (E127) and gelatin.

What IMODIUM® ORIGINAL look like and contents of the pack
IMODIUM® ORIGINAL hard capsules are green/grey capsules marked 'IMODIUM® ORIGINAL' and 'JANSSEN'. They are available in blister packs of 6 capsules.

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