

IMODIUM CAPSULE®

Consumer Medication Information Leaflet (RiMUP)

Loperamide Hydrochloride (2mg)

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What IMODIUM® is used for

IMODIUM® is used for diarrhoea. You may also be given IMODIUM® to reduce the number and volume of stools when you have part of your intestines removed, as this often causes diarrhoea.

How IMODIUM® works

IMODIUM® makes the stools more solid and less frequent by reducing the intestinal muscles movement and increase the time for food to remain in the gastro-intestinal tract.

Before you use IMODIUM®

- When you must not use it
- If there is blood in the stools or you have a high body temperature.
- If you have an inflammation of the small and/or large intestine.
- If your doctor has told you that you have a condition where slowing of the intestine movement should be avoided, for example, if you are constipated or your abdomen is swollen.
- If you know you are hypersensitive (allergic) to loperamide hydrochloride or one of the other ingredients.
- Not recommended for children under 6 years of age.

Pregnancy and lactation

If you are, or think you may be pregnant, you should inform your doctor, who will decide if you can take IMODIUM®.

- Before you start use it

- Tell your doctor if you have allergies to any other medicines, foods, preservatives, or dyes.
- Appropriate fluid and electrolyte therapy should be taken to protect against

dehydration in all cases of diarrhoea especially children.

- If no improvement within 48 hours for an acute diarrhea or if you suffer from liver impairment, do not take any more capsules and consult your doctor.

- Taking other medicines

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

- Ritonavir (used to treat Human Immunodeficiency Virus (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)

If in doubt, consult your doctor or pharmacist. Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use IMODIUM®

- How much to use

The amount of IMODIUM® that you will need to take will depend on your age and the type of diarrhoea.

IMODIUM® should be taken with liquid.

Adults (including elderly)

Acute (sudden onset) diarrhoea: Take 2 capsules at once, then take 1 capsule after every loose stool.

Persistent diarrhoea: Take 2 capsules at once, then adjust the dose until 1-2 solid stools a day are obtained. The right dose should be worked out in consultation with your doctor.

Do not take more than 8 capsules in any 24 hours period.

Children aged 6 years and over

Acute diarrhoea: Take 1 capsule to begin with, then 1 capsule after each loose stool.

Persistent diarrhoea: Take 1 capsule at once, then adjust the dose until 1-2 solid stools a day are obtained. 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 (3 capsules/20kg) but should not exceed 8 capsules per day.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking IMODIUM® for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

- If you use too much (overdose)

If you have taken too many IMODIUM®, call a doctor, especially if you have any of the following symptoms:

- muscle stiffness,
- uncoordinated movements,
- drowsiness,
- difficulty urinating
- weak breathing,
- changes to your heartbeat such as increased heart rate and irregular heart rhythm (these symptoms can have potentially serious, life-threatening consequences).

Children react more strongly to large amounts of IMODIUM® than adults. If a child takes too much or shows any of the above symptoms, call a doctor immediately.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking IMODIUM®.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give IMODIUM® to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Tiredness, dizziness, or drowsiness can be seen with diarrhoea. Therefore, it is advisable to use caution when driving or operating machinery.

Side effects

Like all medicines, IMODIUM® can cause side effects, although not everybody gets them.

Stop using IMODIUM® 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, shortening of breath, hives (also known as nettle rash), 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 distention or swelling or fever which may be due to a blocked or enlarged bowel.
- 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).

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

- Dry mouth, indigestion, stomach pain, discomfort or distension (bloating), feeling sick, vomiting, flatulence, constipation.
- Headache, dizziness, tiredness.
- Rash.
- Difficulty urinating or passing water.
- Constriction of the eye pupils.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of IMODIUM®

- Storage

Do not use IMODIUM® after the expiry date, even if it has been stored properly.

Keep out of the reach and sight of children.

Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

White powder in capsule with opaque green and opaque dark green colour.

- Ingredients

- Active ingredient Loperamide hydrochloride

- Inactive ingredients

Talc, Magnesium Stearate, Maize Starch, Lactose Monohydrate.

- MAL number:

MAL19871473ARZ

Manufacturer

JNTL Consumer Health (France) SAS
Domaine de Maigremont,
27100 Val de Reuil, France.

Product Registration Holder

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