

PACKAGE LEAFLET: INFORMATION FOR THE USER

Imodium[®] 1 mg/5 ml oral solution

Loperamide hydrochloride

Imodium is a registered trademark

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

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you. 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- 1 What Imodium oral solution is and what it is used for
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1 What Imodium oral solution is and what it is used for

The name of your medicine is Imodium 1mg/5ml oral solution. It is called Imodium oral solution in this leaflet.

What Imodium oral solution is used for

Imodium oral solution is used:

- To treat sudden short-lived (acute) attacks of diarrhoea in adults and children over 4 years of age
- To treat long-lasting (chronic) diarrhoea in adults

If your child is using Imodium oral solution, the 'you' stated everywhere below should be read as 'your child'.

How Imodium oral solution works

Imodium oral solution contains 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 use Imodium oral solution

Do not use Imodium oral solution:

- If you are allergic to anything in Imodium oral solution (listed in section 6 below)

- If you have severe diarrhoea after taking antibiotics
- If you are having a flare up of ulcerative colitis
- If you are constipated or your stomach appears swollen
- For a child less than 4 years old

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 oral solution.

Warnings and precautions

Check with your doctor before using Imodium oral solution 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
- You suffer from liver problems
- You have AIDS and your stomach becomes swollen. Stop taking the oral solution immediately and contact your doctor

You may still be able to use Imodium oral solution, but you should discuss this with your doctor first.

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 oral solution.

Replacing fluid and salts

Imodium oral solution only treats the symptoms of diarrhoea. When you have diarrhoea, 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.

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 diarrhoea.

Other medicines and Imodium oral solution

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

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

Tell your doctor before taking Imodium oral solution if you are pregnant, think you may be pregnant or might become pregnant.

Do not take this medicine if you are breast-feeding as small amounts may get into your breast milk. Talk to your doctor about a suitable treatment.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

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.

Imodium oral solution contains

- glycerol: may cause headache, stomach upset and diarrhoea
- sodium saccharin (4.85 mg of sodium in 5 ml): To be taken into consideration by patients on a controlled sodium diet
- methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216). These may cause an allergic reaction. This reaction may happen some time after you have taken Imodium oral solution
- cochineal red A (E124) which may cause allergic reactions
- small amounts of ethanol (alcohol), less than 100 mg per dose

3 How to use Imodium oral solution

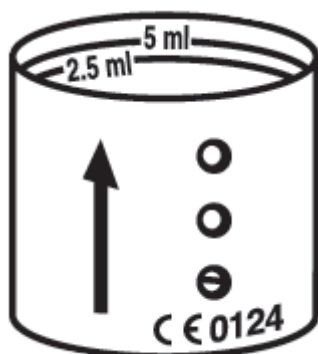
Always use Imodium oral solution exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth
- Swallow the correct number of 5 ml doses of the oral solution

How to use the measuring cup

The measuring cup provided is marked with a 5 ml graduation line. Keep the measuring cup the same way up as it sits on the bottle cap. To be certain that you fill the correct side, make sure that the side with the graduations (the side that holds less) is uppermost. This is the side you have to fill. The arrow on the side should also be pointing up.



How much to take

The dose of Imodium oral solution that you will need will depend on whether your diarrhoea is a sudden attack (acute) or a long-lasting condition (chronic).

Short-lived (acute) diarrhoea

Adults

- Take four 5 ml doses (20 ml) of the oral solution straight away

- From then on take two 5 ml doses (10 ml) after each episode of diarrhoea
- Never take more than sixteen 5 ml doses (80 ml) of the oral solution in any 24 hour period

Children aged 9 and above

- Take two 5 ml doses (10 ml) of the oral solution 4 times a day until diarrhoea is controlled

Children aged 4-8 years old:

- Take one 5 ml dose of the oral solution 3 to 4 times a day until the diarrhoea is controlled

If you are not getting better within 2 days of taking your first dose of Imodium oral solution, stop taking this medicine and go back to your doctor. He or she may want to examine you to check on why you have diarrhoea.

Long-lasting (chronic) diarrhoea

Adults

- Your doctor will tell you how much Imodium oral solution to take. This will depend on how serious your condition is
- You will probably start with a dose of between four to eight 5 ml doses (20 ml to 40 ml) spread out over a day
- Your doctor will find the dose that suits you best. He or she may then suggest you take the oral solution twice a day
- Never take more than sixteen 5 ml doses (80 ml) of the oral solution in any 24 hour period

Children

- Imodium oral solution is not recommended for long-lasting (chronic) diarrhoea in children

If you forget to take Imodium oral solution

- 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 use more Imodium oral solution than you should

If you have taken too much Imodium oral solution, 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 oral solution 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, this medicine can cause side effects, although not everybody gets them.

Stop using Imodium oral solution 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)

Tell your doctor if you notice any of the following side effects while using Imodium oral solution:

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 fewer than 1 in 1000 patients)

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

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

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 the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard

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

5 How to store Imodium oral solution

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

Do not use Imodium oral solution after the expiry date which is stated on the label. 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 oral solution contains

- **The active substance** is loperamide hydrochloride.
Each 5 ml dose of oral solution contains 1 mg loperamide hydrochloride. (The oral solution contains 0.2 mg of loperamide hydrochloride in each millilitre.)
- **The other ingredients** are glycerol, sodium saccharin, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), cochineal red A (E124), raspberry flavour, redcurrant flavour, ethanol, citric acid and water.

What Imodium oral solution looks like and contents of the pack

Imodium oral solution is a red, fruit-flavoured, sugar-free oral solution. It is available in 100 ml amber glass bottles with a plastic measuring cup.

Marketing Authorisation Holder:

Janssen-Cilag Ltd, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire HP12 4EG, UK

Manufacturer:

Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium

OR

McGregor Cory Ltd, Middleton Close, Banbury, Oxfordshire OX 16 4RS, UK

For information in large print, tape, CD or Braille, telephone 0800 7318450.

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