

IMODIUM[®] Capsules & Caplets

IMODIUM[®] Melts

Loperamide hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about IMODIUM. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking IMODIUM against the benefits this medicine is expected to have for you.

If you have any concerns about using IMODIUM ask your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What IMODIUM is used for

IMODIUM is used to treat sudden (acute) diarrhoea or long-lasting (chronic) diarrhoea.

IMODIUM is also used in patients who have had part of their intestines removed by surgery (intestinal resection).

IMODIUM makes the stools more solid and less frequent. It does this by normalising the muscle contractions of the intestine. This allows the bowel time to absorb water and produce a more solid stool.

Your doctor may have prescribed IMODIUM for another reason. **Ask your doctor if you have any questions about why IMODIUM has been prescribed for you.**

Before you take IMODIUM

When you must not take it:

Do not take IMODIUM if:

- you have an allergy to IMODIUM or any of the ingredients listed at the end of this leaflet (see **Product Description**).
- you are constipated, or have to avoid becoming constipated
- you have severe diarrhoea with blood in the stools or fever
- you have inflammation of the lower bowels (for example, ulcerative colitis or pseudomembranous colitis as a result of using antibiotics)
- you are breast-feeding
- the packaging is torn or shows signs of tampering

Do not use IMODIUM after the expiry date (month and year) printed on the pack. If you take IMODIUM after the expiry date it may not work.

Do not give IMODIUM to children under the age of 12 years.

Before you start to take it:

You must tell your doctor or pharmacist if you:

- are pregnant or planning to become pregnant
- are breastfeeding
- have or have ever had liver disease
- have kidney disease
- have AIDS (Acquired Immune Deficiency Syndrome)
- have glaucoma (high pressure in the eye)
- have bladder problems
- regularly drink a lot of alcohol.

Taking other medicines:

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

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

- sleeping tablets or medicines to treat anxiety and nervousness
- medicines to treat depression
- medicines that slow down the action of the stomach and intestines.

Taking IMODIUM

How to take:

IMODIUM capsule and caplet should be swallowed with the aid of liquid.

IMODIUM Melts should be placed on the tongue, allowed to dissolve and swallowed with saliva. No liquid intake is necessary.

How much to take:

Adults:

Sudden (acute) diarrhoea

The usual adult dose is two IMODIUM capsules or caplets or Melts initially, followed by one capsule or caplet or Melt after each loose unformed stool as needed. **Do not take more than eight capsules or caplets or Melts in one day.**

Your doctor may prescribe a different dose for you.

IMODIUM will usually stop the symptoms of diarrhoea within 48 hours. If it does not, stop taking the medicine and see your doctor.

Chronic diarrhoea and intestinal resection

The usual adult dose is two IMODIUM capsules or caplets or Melts initially, followed by one capsule or caplet after each loose unformed stool until the diarrhoea is under control. Your doctor will then adjust the dose of IMODIUM to suit you.

Children:

IMODIUM should not be given to children under 12 years of age.

If you forget to take it:

If you forget to take IMODIUM after an unformed stool, take it when you remember or after your next unformed stool.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, check with your doctor or pharmacist.

If you have taken too much (overdose):

Immediately telephone your doctor or the Poisons Information Centre for advice, or go to Accident and Emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Poisons Information Centre telephone numbers:

- Australia: 13 11 26
- New Zealand: 0800 POISON or 0800 764 766

Keep these telephone numbers handy in case of an emergency.

If you take too much IMODIUM you may have any of the following symptoms: sleepiness, nausea and vomiting, constipation, difficulty passing urine, weak breathing, muscle stiffness and uncoordinated movements.

Children are more sensitive than adults to medicines such as IMODIUM. An accidental overdose is especially dangerous. Make sure IMODIUM is kept out of reach of children.

While you are using IMODIUM

Things you must do:

- If you do not improve after taking IMODIUM for 48 hours tell your doctor or pharmacist
- Drink plenty of fluids, to avoid dehydration
- Tell your doctor if you become pregnant while taking IMODIUM
- Tell your doctor or pharmacist that you are taking IMODIUM if you are about to start taking a new medicine.

Things you must not do:

- Do not take more than 8 capsules or caplets in one day
- Do not use IMODIUM to treat any other complaint unless your doctor says so
- Do not give this medicine to anyone else, even if they have the same symptoms as you.

Things to be careful of:

Effects on driving and operating machinery

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

Side Effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you experience any of the following and they worry you:

- nausea or vomiting
- constipation
- dry mouth or bad taste
- headache
- stomach pain
- flatulence (wind)
- difficulty passing urine
- tiredness
- dizziness or drowsiness.

These side effects are usually mild. The above list does not represent all side effects that have been reported for IMODIUM. If you notice any side effects not mentioned in this leaflet, please inform your pharmacist or doctor.

Tell your doctor immediately and do not take your next dose of IMODIUM if you experience:

- asthma, wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- sudden or severe blisters, itching, skin rash, hives
- flaking or peeling of skin.
- Loss of or depressed level of consciousness

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

Other side effects not listed above may also occur in some people. **Tell your doctor if you notice anything making you feel unwell when you are taking, or soon after you have finished taking IMODIUM.**

Ask your pharmacist or doctor if you do not understand anything in this list.

After using IMODIUM

Storage

Keep your IMODIUM Capsules and Caplets in a cool dry place where the temperature stays below 30°C.

Keep your IMODIUM Melts in a cool dry place where the temperature stays below 25°C.

Do not store IMODIUM, or any other medicine, in the bathroom or near a sink. Do not leave medicines in the car or on window sills. Heat and dampness can destroy some medicines.

Keep your medicines where children cannot reach them. A locked cupboard at least one-and-a-half metres (1.5 m) above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking IMODIUM or they have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product Description

What IMODIUM looks like:

IMODIUM capsules are small grey/green capsules.

Each pack contains 12 capsules.

IMODIUM caplets are light green, capsule-shaped tablet, marked with IMODIUM A-D on one side, scored on the other side and marked with 2 mg.

Each pack contains 8 or 20 caplets.

IMODIUM Melts are white to off-white circular tablets.

Each pack contains 10 tablets.

Ingredients

Each IMODIUM Capsule contains 2 mg of loperamide hydrochloride as the active ingredient.

The capsules also contain lactose, maize starch, purified talc and magnesium stearate, iron oxide yellow (E172), indigo carmine (E132), erythrosine (E127), titanium dioxide (E171) and gelatin.

The capsules do not contain gluten.

Each IMODIUM Caplet contains 2 mg of loperamide hydrochloride as the active ingredient.

The caplets also contain cellulose microcrystalline, dibasic calcium phosphate, magnesium stearate, silica, quinoline yellow (E104) and brilliant blue FCF (E133).

The caplets do not contain lactose or gluten.

Each IMODIUM Melts contains 2mg of loperamide hydrochloride as the active ingredient.

The Melts also contain gelatin, mannitol, aspartame, sodium bicarbonate and peppermint 51296 TP0551 flavour.

The Melts do not contain lactose or gluten.

Sponsor

Johnson & Johnson Pacific
45 Jones Street
Ultimo NSW 2007
Australia

For further enquiries call our Toll Free Free Info Line
Aus 1800 029 979
NZ 0800 446 147

Australian Register Number:
IMODIUM capsules – AUST R 13303
IMODIUM caplets – AUST R 56001
IMODIUM Melts – AUST R 83176

This leaflet was prepared in March 2009.