

Loperamide hydrochloride (HCl)

Imodium® capsules

WHAT IS IMODIUM® FOR

IMODIUM® is used to treat diarrhea. IMODIUM® makes the stools more solid and less frequent.

You can take IMODIUM® 2MG CAPSULE for **sudden (acute) diarrhea or long-lasting (chronic) diarrhea**.

You may also be given IMODIUM® 2MG CAPSULE if you have part of your intestines removed, as this often cause diarrhea.

WHEN NOT TO TAKE IMODIUM® 2MG CAPSULE

Do not give IMODIUM® 2MG CAPSULE to **children under 2 years**. Do not use IMODIUM® 2MG CAPSULE:

- If there is **blood in your stools** or you have a **high temperature**;
- If you have **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 you know you are **allergic (hypersensitive)** to loperamide HCl or one of the other ingredients.

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

WHAT SPECIAL PRECAUTIONS SHOULD YOU TAKE?

- Although IMODIUM® 2MG CAPSULE stops diarrhea, it will not treat the cause of it. Whenever possible, the cause of the diarrhea should also be treated.
- When you have diarrhea, you will lose a lot of fluids. You should therefore **replace lost fluids by taking much more liquid than you normally would**. This is especially important for small children. Your pharmacist will be able to supply a special powder that contains sugar and salts. When added to water, it will also replace the salts that are lost during a bout of diarrhea. This solution is particularly suitable for children.
- **For sudden (acute) diarrhea, IMODIUM® 2MG CAPSULE will usually stop the symptoms within 48 hours. If it does not, stop taking the medicine and see your doctor.**
- If you have AIDS and are being treated with IMODIUM® 2MG CAPSULE for diarrhea and if you have any signs of abdominal swelling or bulging, stop taking IMODIUM® 2MG CAPSULE immediately and tell your doctor.
- Do not take this product for anything other than its intended use and never take more than the recommended amount. 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® 2MG CAPSULE.
- Do not abuse and misuse IMODIUM® 2MG CAPSULE.

Children

IMODIUM® 2MG CAPSULE should not be given to children under 2 years and should only be given to children under 6 years if your doctor has prescribed it.

Pregnancy

If you are, or think you may be, pregnant, you should inform your doctor, who will decide if you can take IMODIUM® 2MG CAPSULE.

Breast-feeding

You are advised not to take IMODIUM® 2MG CAPSULE if you are breast-feeding, because small amounts of IMODIUM® 2MG CAPSULE can end up in your milk.

Driving or operating machinery

Tiredness, dizziness, or drowsiness can be seen with diarrhea. If this happens, do not drive or use any machines.

Other medicines

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. 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)

Liver problems

- Tell your doctor if you have liver problems; you may need close medical supervision while you are taking IMODIUM® 2MG CAPSULE.

HOW TO TAKE IMODIUM® 2MG CAPSULE AND HOW MUCH

The dose of IMODIUM® 2MG CAPSULE that you will need to take will depend on your age and the type of diarrhea.

IMODIUM® 2MG CAPSULE is to be taken by mouth. You can take IMODIUM® 2MG CAPSULE at any time of day. The capsules should be taken with liquid.

Capsules

Adults (including elderly)

- For sudden (acute) diarrhea, 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 long-lasting (chronic) diarrhea, the right dose should be worked out with your doctor.

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

Children aged 6 years and over

- For sudden (acute) diarrhea, 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) diarrhea, the right dose should be worked out in consultation with your doctor.

But: 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® 2MG capsules per day
from 14 kg	never more than 2
from 20 kg	never more than 3
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.

UNDESIRE EFFECTS

Like all medicines, IMODIUM® 2MG CAPSULE can cause side effects, although not everybody gets them.

Stop using IMODIUM® 2MG CAPSULE 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 or urticaria), severe itching, 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, increased muscle tone or muscle rigidity, 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® 2MG CAPSULE:

- Dry mouth, indigestion, stomach pain, discomfort or bloating, feeling sick, vomiting, passing wind, constipation.
- Headache, feeling dizzy, feeling sleepy or tired, feeling weak.
- Rash
- Urinary retention (being unable to pass urine or empty the bladder completely)
- Constricted 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.

OVERDOSE

If you have taken too much IMODIUM® 2MG CAPSULE, immediately contact a doctor or hospital for advice, especially 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, uncoordinated movements, drowsiness, difficulty urinating or weak breathing.

Children react more strongly to large amounts of IMODIUM® 2MG CAPSULE than adults. If a child takes too much or shows any of

the above symptoms, call a doctor immediately. Abuse, misuse and/or overdose with excessively large doses of loperamide, may unmask abnormal heart rhythm that is potentially life threatening. Upon cessation, cases of drug withdrawal syndrome have been observed in individuals abusing, misusing or intentionally overdosing with excessively large doses of loperamide.

Information for the doctor in case of overdose:

- Inject naloxone.
- Repeat injections of naloxone after 1-3 hours if needed.
- ECG monitoring for QT interval prolongation should be initiated.
- Monitoring for at least 48 hours is required.

HOW TO STORE IMODIUM® 2MG CAPSULE

Store at or below 30°C. Keep out of reach of children. This medicine can be kept for only a limited period. See expiry date on the outer pack. Do not use IMODIUM® 2MG CAPSULE after the date (month and year) printed after "EXP", even if it has been stored properly.

WHAT IS IN IMODIUM® 2MG CAPSULE?

IMODIUM® 2MG CAPSULE is a medicine to treat your diarrhea. The active ingredient is **loperamide**.

IMODIUM® capsules

- IMODIUM® capsules are white powder filled in capsules with green cap and dark grey body.
- They come in packs of 240, 18 or 6 capsules.
- One capsule contains 2 milligrams of loperamide hydrochloride.
- The capsule also contains lactose monohydrate, maize starch, talc and magnesium stearate. The capsule itself is made from iron oxide yellow, black ferrous oxide, indigotindisulphonate sodium, erythrosine sodium, titanium dioxide and gelatin.

What you should know about medicines ...

Always inform your doctor or pharmacist if you are using other medicines because some drugs should not be taken together.

It is important that you use medicines correctly. That is, you should:

- Always carefully read the full patient information leaflet;
- Use medicines only for the purpose for which you were given the medicine;
- Use medicines only in the prescribed amount;
- Use medicines only for the prescribed period of time.

Keep all medicines out of the reach of children.

Never allow others to use medicines recommended for you and never use medicines prescribed for others.

Keep all medicines in their original packaging and in a dry place (never in the bathroom, for example!).

If someone has taken an overdose of a medicine, call a doctor.

Product Registrant:

Johnson & Johnson Pte. Ltd.
2 Science Park Drive, #07-13, Ascent,
Singapore Science Park 1, Singapore 118222
Singapore Consumer Hotline: 800-601-1460

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SG1000611

254.706 mm

134.761 mm

1 mm

 CREATIVE SPREADPRINT PTE LTD	
Item Number : SG1000611	J&J
Material : 50gsm Woodfree	
Dimension : 254.706 x134.761mm	
Finishing : Folded	
Version : 2	Date : 25/NOV/2021
Color Code :  BLACK	
Name : Sin Yi	Approve :
Date : 10/NOV/2021	Date :

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