Fonts : Arial

Fonts Size :
Generic Name font size : 11 pt.
Composition fonts size : 9 pt.

Loperamide 2 mg Capsules (POM)

Leaflet Size : 150 x 285 mm
MPLLLOP0002CPCOMFPLXXX071V05

150 mm

285 mm

PHARMA CODE

XXXX

Pharmacode Reading Direction

PACKAGE LEAFLET: INFORMATION FOR THE USER
Loperamide 2 mg Capsules, Hard
(loperamide hydrochloride)

Read all of this leaflet carefully before you start taking 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 only. 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 Loperamide Capsule is and what it is used for
2.What you need to know before you take Loperamide Capsules
3.How to take Loperamide Capsules
4.Possible side effects
5.How to store Loperamide Capsules
6.Contents of the pack and other information

1. WHAT LOPERAMIDE CAPSULE IS AND WHAT IT IS USED FOR

Loperamide capsule is used
- To treat sudden short-lived (acute) attacks of diarrhoea in adults and in children over 9 years of age.
- To treat long lasting (chronic) diarrhoea in adults

Loperamide capsules contain *loperamide hydrochloride*, a substance that helps reduce diarrhoea by slowing down an overactive bowel. This allows water and salts that are usually lost in diarrhoea to be absorbed by the body.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LOPERAMIDE CAPSULES

Consult a doctor before use if you have a history of drug abuse; loperamide is an opioid and addiction is observed with opioids as a class.

Do not take Loperamide capsules
- If you are allergic to loperamide hydrochloride or any of the ingredients of this medicine (listed in section 6).
- If you have severe diarrhoea after taking antibiotics.
- If you are having a flare-up of an inflammatory bowel condition like ulcerative colitis.
- If you are constipated or your stomach appears swollen (especially in children with severe dehydration).
- for a child less than 9 years old.
- If you have acute dysentery, the symptoms of which may include blood in your stools and a high temperature

Do not use this medicine if any of these applies to you. If you are not sure, talk to your doctor or pharmacist before taking Loperamide Capsules.

Warnings and precautions
Talk to your doctor before taking Loperamide Capsules 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 have AIDS and your stomach becomes swollen, stop taking the capsules immediately and contact your doctor.
- You suffer from liver problems.

You may still be able to use Loperamide capsules, 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 Loperamide Capsules.

Replacing fluid and salts
Loperamide capsules only treats the symptoms of diarrhoea. Your body can lose large amounts of fluids and salts when you have diarrhoea. You need to replace the fluid by drinking more liquid than usual. 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. The prevention of fluid depletion (dehydration) is particularly important in infants, children, and frail and elderly people with acute diarrhoea.

Other medicines and Loperamide Capsules
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

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).
- Oral desmopressin (used to treat excessive urination).
- Itraconazole, ketoconazole (used to treat fungal infections).
- gemfibrozil (used to treat high cholesterol).
- other drugs that slow down or speed up movement in the gut

Pregnancy and breast-feeding
If you are pregnant, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Do not take this medicine if you are breast-feeding as small amounts may get into your milk.
Talk to your doctor about a suitable treatment.

Driving and using machines
Do not drive if you feel dizzy, tired or sleepy. You may feel less alert, feel faint or pass out. If you're affected do not drive or use machines.

Loperamide capsules 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 LOPERAMIDE CAPSULES

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The dose of Loperamide capsules that you will need will depend on whether your diarrhoea is a sudden, short lived attack (acute) or a long-lasting condition (chronic).

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

Short-lived (acute) diarrhoea
Adults and children over 12 years:
- Take two capsules to begin with and then one capsule after each episode of diarrhoea for up to 5 days.
- Never take more than 8 capsules in any 24 hour period.

Children aged 9-12 years:
- Take one capsule 4 times daily until diarrhoea is controlled or for up to 5 days.
- Never take more than this dose.

Children aged under 9 years old:
This medicine should not be given to children under 9 years old. Other pharmaceutical forms/strengths (e.g. syrup) are available for children aged 4 years and over.
If your symptoms are not getting better within 2 days of taking your first dose of this medicine, you should see your doctor again, who may want to examine you to further check on the cause of the diarrhoea.

Long-lasting (chronic) diarrhea
Adults only:
- Your doctor will tell you how much Loperamide capsules to take.
- The initial dose will probably be between two and four capsules per day taken in divided doses, but will depend on each individual's needs. When your doctor is satisfied that you are receiving the daily dose that best suits you, he or she will then probably suggest that you take your capsules twice a day.
- Never take more than 8 capsules in any 24 hour period.

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

If you forget to take Loperamide capsules
- 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 a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Loperamide Capsules can have side-effects, like all medicines, although these don't affect everyone and most are usually mild.
Get medical help at once
Rare: (may affect up to 1 in 1,000 people)
- Allergic reactions including unexplained wheezing, shortness of breath, passing out or swelling of face and throat.
- Skin rashes, which may be severe and include blistering or peeling skin.
- Loss of consciousness or reduced level of consciousness (passing out, feeling faint or less alert), uncoordinated movements.

If you get any of these, **stop using the medicine and get medical help at once.**

Talk to a doctor as soon as possible

Uncommon: (may affect up to 1 in 100 people)
- Itchiness or hives.
- Stomach pain or swollen stomach.

Rare: (may affect up to 1 in 1,000 people)
- Difficulties passing water.
- Severe constipation.
- Miosis (narrowing of the pupils of the eye).

If you notice any of the above, stop using the medicine and talk to a doctor.

Other effects that may occur
Common: (may affect up to 1 in 10 people)
- Feeling sick, constipation or wind.
- Headache.

Uncommon: (may affect up to 1 in 100people)
- Dizziness or drowsiness.
- Vomiting, indigestion.
- Dry mouth.

Rare: (may affect up to 1 in 1,000 people)
- Tiredness.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE LOPERAMIDE CAPSULES

Keep this medicine out of the sight and reach of children.
Store below 25°C. Store in the original package.
Do not use this medicine after the date shown as the expiry date on the packaging.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Loperamide Capsules contains
The active ingredient in Loperamide Capsules is: Loperamide hydrochloride 2 mg per capsule.
The other ingredients are lactose monohydrate, microcrystalline cellulose, maize starch, colloidal anhydrous silica, purified talc, magnesium stearate. The capsule is made up of gelatin, water, sodium lauryl sulfate, patent blue V (E131), quinoline yellow (E104), brilliant blue FCF (E133), iron oxide red (E172) and titanium dioxide (E171).
The printing ink contains shellac (E904), propylene glycol (E1520), black iron oxide (E172) and potassium hydroxide (E525).

What Loperamide Capsules looks like and contents of the pack
Loperamide Capsules are Size '4' Hard gelatin capsule with Green cap imprinted with 'L' in black ink and grey body imprinted with '2mg' in black ink, containing white to off-white powder.
Loperamide Capsules are available in blister packs of 2, 4, 6, 8, 12, 18 and 30 capsules (not all pack sizes may be marketed).

Marketing Authorisation Holder:
Flamingo Pharma (UK) Ltd.
1st Floor, Kirkland House, 11-15 Peterborough Road, Harrow, Middlesex, HA1 2AX,
United Kingdom.

Manufacturer:
Flamingo Pharma (UK) Limited
The Bloc, 38 Springfield Way,
Anlaby, Hull, HU10 6RJ, United Kingdom

If you would like this leaflet in different format information or want to report any side effects please contact marketing authorization holder listed above.

This leaflet was last revised in 12/2020.

POM

PL 43461/0011

MPLLLOP0002CPCOM
FPLXXX071V05

Code : MPLLLOP0002CPCOMFPLXXX071V05				Customer / Livery : FPL UK	
Colour Scheme : Black				Ref. Artwork : MPLLLOP0002CPCOMFPLXXX071V04	
Prepared By	**Reviewed & Checked By**			**Approved by**	
Artwork	**Pkg. Development**	**Regulatory**	**Marketing**	**CQA**	**MAH**
Sign.	Sign.	Sign.	Sign.	Sign.	Sign.
Date :	**Date :**	**Date :**	**Date :**	**Date :**	**Date :**