

Package leaflet: Information for the user

Loperamide 2mg Hard Capsules

Read all of this leaflet carefully because it contains important information for you.

- This medicine is available without prescription. However, you still need to take Loperamide Capsules carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Ask your doctor or pharmacist if you need more information or advice.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Loperamide Capsules are and what they are used for
2. Before you take Loperamide Capsules
3. How to take Loperamide Capsules
4. Possible side effects
5. How to store Loperamide Capsules
6. Further information

1. WHAT LOPERAMIDE CAPSULES ARE AND WHAT THEY ARE USED FOR

Loperamide capsules contain the active ingredient loperamide hydrochloride. Loperamide belongs to a group of medicines called 'anti-diarrhoeals' which are used to treat diarrhoea. Loperamide is used to treat sudden acute cases of diarrhoea in adults and children over 12 years of age. It reduces diarrhoea by slowing down an overactive bowel. It also helps the body to absorb more water and salts from the bowel.

2. BEFORE YOU TAKE LOPERAMIDE CAPSULES

Do not take Loperamide Capsules if:

- you are allergic to loperamide or any of the other ingredients (see section 2 'Important information about some of the ingredients' and section 6 'Further information')
- you need to keep the bowel movements normal to avoid complications such as blockage of the bowel and abnormal or rapid widening of the colon
- you have constipation, blockage of the bowel or a bloated tummy (in particular, in children with severe dehydration). Symptoms of dehydration may include drowsiness, passing little urine, dry mouth/tongue, unresponsiveness or glazed eyes)
- you have inflammation or irritation of the bowel e.g. diverticulosis, colitis or bacterial enterocolitis caused by Salmonella, Shigella or Campylobacter (symptoms may include watery or bloody diarrhoea)
- you have symptoms of dysentery, which may include blood in your stools and a high temperature
- you have irritable bowel syndrome

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

Take special care if:

- you have or think you may have lost body fluids and salts through diarrhoea.

Particularly important for children and frail or elderly patients with severe diarrhoea (see 'Replacing fluids and salts', section 3)

- you have liver disease
- you have inflammatory bowel disease
- you have AIDS. You must stop taking loperamide at the earliest signs of abnormal distension.

Since persistent diarrhoea can be an indicator of potentially more serious conditions, loperamide should not be used for prolonged periods of time.

You should consult your doctor or pharmacist before taking loperamide as it may cause side effects

If any of the above apply to you, please consult your doctor or pharmacist.

Taking other medicines

Loperamide may interact with other medicines. If you are taking other medicines, including medicines obtained without a prescription and you are unsure about taking loperamide, you should contact your doctor or pharmacist.

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

- co-trimoxazole, an antibiotic, used in the treatment of bacterial infections such as chronic bronchitis
- quinidine, used in the treatment of an abnormal heart beat
- ritonavir, used in the treatment of HIV infection and AIDS
- oral desmopressin, used in the treatment of diabetes and bedwetting.

Pregnancy and breast-feeding

If you are pregnant or planning to become pregnant, do not take Loperamide Capsules. It is not known if it safe to take. If you are breast-feeding, you should consult your doctor or pharmacist before taking, as small amounts of this medicine may get into your breast milk.

Driving and using machines

This medicine may make you feel tired, dizzy or drowsy.

If affected, do not drive or operate machinery or take part in activities where such effects could put yourself or others at risk.

Important information about some of the ingredients

This product 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

Follow the instructions below or ask your pharmacist for help if you are not sure how to take this medicine.

- For oral administration.
- Swallow whole with a drink.

Adults and children over 12 years:

Two capsules initially followed by one capsule after each period of diarrhoea, for up to 24 hours.

Do not take more than six capsules in any 24-hour period.

Children under 12 years:

This medicine should **not** be given to children under 12 years of age.

Do not take Loperamide for longer than 24 hours. If your symptoms do not improve within 24 hours, please contact your doctor.

Replacing fluids and salts

When you have diarrhoea you lose large amounts of fluid and salts and can become dehydrated so, in addition to this medicine you need to take in more liquids than usual. You are more likely to become dehydrated if you are also vomiting.

- Take small frequent sips of water or diluted fruit juice.
- If there are signs of dehydration (drowsiness, passing little urine, dry mouth/tongue, unresponsiveness or glazed eyes), particularly in a child, or in frail or elderly people contact your doctor or pharmacist immediately
- If you are worried about becoming dehydrated, the doctor/pharmacist may advise rehydration drinks. These can be obtained from the pharmacy/chemist and provide the correct balance of water, salt and sugar.
- Avoid drinking very large amounts of plain water
- Do not drink alcohol or milk
- As soon as you feel like it eat. The best foods to start with are those high in carbohydrates (such as plain bread, pasta, rice or potatoes) and soup. Avoid fatty foods, and fruit and vegetables at first.
- Within a couple of days of the symptoms resolving, you should be back on your normal diet

If you take more Loperamide Capsules than you should

Contact your doctor or go to your nearest casualty department immediately. Take the container and this leaflet with you so that people will know what you have taken.

If you forget to take Loperamide Capsules

Take it as soon as you remember. Never double up a dose to make up for the dose you have missed.

4. POSSIBLE SIDE EFFECTS

Like all medicines Loperamide Capsules can cause side effects, although not everybody gets them.

Stop taking your medicine and contact your doctor immediately or nearest hospital if you experience the following (very rare side effects):

- Allergic reactions which can produce swelling of the face, eyes, tongue and/or lips, difficulty breathing and/or swallowing or itching
- Severe skin rashes including blistering of skin, mouth, eyes and genitals
- Severe tummy pains with bloating/swelling or increasing diarrhoea particularly if this contains blood

Frequent side effects of diarrhoea

- being sick (vomiting)
- stomach cramps
- feeling sick (nausea)
- tiredness
- stomach pains
- flatulence (passing wind)
- indigestion

- drowsiness
- urinary retention (unable to pass urine)
- rash
- itching
- skin lesions
- Stevens-Johnson Syndrome (serious illness with blistering of the skin, mouth, eyes and genitals)
- toxic epidermal necrolysis (serious illness with blistering of the skin)
- necrotising enterocolitis (serious inflammation of the bowel)
- megacolon including toxic megacolon (abnormal enlargement of the intestines)
- dry mouth

Side effects reported with greater frequency

- constipation
- dizziness

If any of the side effects listed become serious or you notice any side effects not listed, please contact your doctor or pharmacist.

5. HOW TO STORE LOPERAMIDE CAPSULES

Keep out of the reach and sight of children.

Store in the original container in order to protect from moisture.

Do not use these capsules after the expiry date shown on the outside packaging.

Return all unused medicines to your pharmacist for safe disposal.

6. FURTHER INFORMATION

What Loperamide Capsules contain:

Active ingredient: Loperamide hydrochloride 2mg

Other ingredients: Maize starch, lactose, povidone, sodium starch glycolate and magnesium stearate. The capsule shell contains gelatin, titanium dioxide (E171), iron oxides (E172) and patent blue V (E131) (see section 2 'Important information about some ingredients').

What Loperamide Capsules look like and the contents of the pack

The medicine is enclosed in a green and dark grey capsule. The pack contains 6 capsules.

Marketing Authorisation Holder

Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK

Manufacturer

CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product Name	Reference Number
Loperamide 2mg Hard Capsules	29831/0131

This leaflet was last revised in February 2011.

104602/3

 **WOCKHARDT**