

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Loperamide hydrochloride 2 mg

Capsules

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 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 is and what it is used for
2. What you need to know before you take Loperamide
3. How to take Loperamide
4. Possible side effects
5. How to store Loperamide
6. Contents of the pack and other information

1. What Loperamide is and what it is used for

Loperamide hydrochloride belongs to a group of medicines called 'antidiarrhoeals' which are used to treat diarrhoea. It reduces diarrhoea by slowing down an overactive bowel. This allows water and salts that are usually lost in diarrhoea to be absorbed by the body.

Loperamide is used to treat:

- Sudden, short-lived (acute) attacks of diarrhoea in adults and children over 9 years of age
- Sudden flare-ups of long-lasting (chronic) diarrhoea in adults

2. What you need to know before you take Loperamide

Do not take Loperamide if:

- You are allergic to Loperamide or any of the other ingredients of this medicine (listed in section 6)
- 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 a flare-up of ulcerative colitis (a form of inflammatory bowel disease) which can cause abdominal pain, bloody diarrhoea, fever and weight loss
- You have severe diarrhoea after taking antibiotics (symptoms may include watery or bloody diarrhoea)
- You have constipation, blockage of the bowel or a bloated tummy
- You have a bacterial infection of the small intestine and colon (caused by bacteria such as salmonella, shigella and campylobacter)
- You have inflammation of the colon after taking antibiotics (symptoms may include watery or bloody diarrhoea)
- You have acute (short-lived) dysentery, the symptoms of which may include blood in your stools and a high temperature

Warnings and precautions

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.

Talk to your doctor before taking Loperamide 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 suffer from liver problems. You should consult your doctor or pharmacist before taking Loperamide as it may cause side effects
- You have a bloated tummy and you have AIDS. You should stop taking this medicine immediately and contact your doctor

Talk to your doctor if there is no improvement in your symptoms within 48 hours of taking Loperamide.

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.

Other medicines and Loperamide

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription. This includes herbal medicines.

Loperamide should **not be taken** with the following:

- Other antidiarrhoea preparations, except for oral rehydration therapy (see 'Replacing fluids and salts' in section 3)

Loperamide **may cause serious side effects** if taken with the following:

- Quinidine, used to treat abnormal heart rhythms or malaria
- Ritonavir, used to treat HIV infection and AIDS
- Itraconazole and ketoconazole, used to treat fungal infections
- Gemfibrozil, used to lower levels of cholesterol and other lipids (fats) in the blood

Loperamide **increases the blood levels** of the following:

- Oral desmopressin, for reducing urine production (antidiuretic)

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, ask your doctor for advice before taking this medicine.

Pregnancy

If you are pregnant or planning to become pregnant, you are advised not to take Loperamide. It is not known if it is safe to take, especially during the first 3 months of pregnancy.

Breast-feeding

If you are breast-feeding, you should not take Loperamide, as small amounts of this medicine get into your breast milk.

Driving and using machinery

This medicine may make you feel tired, dizzy or drowsy. You may feel less alert, feel faint or pass out. If affected, you are advised not to drive or operate machinery.

Loperamide contains Lactose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

Loperamide contains colouring agent Sunset Yellow FCF (E110)

It may cause allergic reaction.

3. How to take Loperamide

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

- Loperamide is for oral use only
- Swallow the capsules whole with some liquid

Short-term (acute) diarrhoea

Adults and adolescents over 17 years:

- 2 capsules (4 mg) initially followed by 1 capsule (2 mg) after each loose stool (bowel movement) for up to 5 days
- The maximum dose is 6 capsules (12 mg) in 24 hours

Use in children (aged 9-17 years):

- 1 capsule (2 mg) initially, followed by 1 capsule (2 mg) after each loose stool (bowel movement) for up to 5 days
- The maximum dose is 6 capsules (12 mg) in 24 hours

Long-lasting (chronic) diarrhoea

Adults only:

- The recommended starting dose is 2 capsules (4 mg) daily
- This initial dose should be adjusted until 1-2 solid stools a day are obtained. This is usually achieved with a maintenance dose of 1-6 capsules (2 mg-12 mg) daily
- The maximum dose is 6 capsules (12 mg) in 24 hours

Loperamide should not be given to children for the treatment of chronic diarrhoea.

Patients with liver problems
See 'Warnings and precautions' (section 2).

Use in children (under 9 years of age):

Loperamide should not be given to children under 9 years of age.

If you have diarrhoea and your symptoms do not improve within 48 hours, you should stop taking Loperamide and contact your doctor.

Replacing fluids and salts
When you have diarrhoea your body loses large amounts of fluid and salts. You should therefore replace this lost fluid by drinking more liquids than normal. Drink plenty of clear fluids containing salt and sugar (special oral rehydration powders are available from pharmacists). This is especially important for children, and frail or elderly people.

If you take more Loperamide than you should

If you have taken too many capsules, immediately contact a doctor or hospital for advice. Remember to take this leaflet with you.

Symptoms (of an overdose) may include: increased heart rate, irregular heartbeat, changes to your heartbeat (these symptoms can have potentially serious, life-threatening consequences), muscle stiffness, unco-ordinated movements, drowsiness, difficulty urinating or weak breathing.

Children react more strongly to large amounts of Loperamide 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:
Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose, **do not** take a double dose to make up for a forgotten dose.

If you stop taking Loperamide
It is important that you keep taking Loperamide for as long as your doctor has told you to.

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

4. Possible side effects

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

Serious side effects
Seek medical advice immediately if you develop the following symptoms:

- Bloating and tenderness of the stomach or fever (megacolon or toxic megacolon)
- Allergic reaction: swelling of the face, throat or tongue, difficulty breathing (anaphylaxis) or dizziness
- Severe blistering of the skin, mouth, eyes and genitals (Steven-Johnson's Syndrome or toxic epidermal necrolysis)
- Fever, general ill feeling, itching, joint aches, multiple skin lesions (erythema multiforme)
- Swelling of the deeper layers of the skin caused by a build-up of fluid (angioedema)
- Loss of consciousness or reduced level of consciousness (passing out, feeling faint or less alert)
- Difficulty co-ordinating movement
- Difficulty in urinating (passing water)
- Severe constipation
- Blockage of the bowel

Other side effects
Common side effects (may affect up to 1 in 10 people)

- Headache
- Dizziness
- Constipation
- Feeling sick (nausea)
- Stomach wind (flatulence)

Hard to read?

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Uncommon side effects (may affect up to 1 in 100 people)

- Drowsiness
- Stomach pain or discomfort
- Dry mouth
- Being sick (vomiting)
- Indigestion
- Rash

Rare side effects (may affect up to 1 in 1,000 people)

- Abnormal increase in muscle tension (hypertonia)
- Bloating and tenderness of the stomach
- Tiredness
- Pupils of the eyes become smaller (miosis)
- Skin rashes with the formation of wheals (urticaria)
- Severe itching (pruritus)

Not known (frequency cannot be estimated from the available data)

- Upper abdominal pain, abdominal pain that radiates to back, tenderness when touching the abdomen, fever, rapid pulse, nausea, vomiting, which may be symptoms of inflammation of the pancreas (acute pancreatitis)

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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

- Keep this medicine out of the sight and reach of children.
- Do not store above 25 °C. Store in the original package in order to protect from light.
- Do not use this medicine after the expiry date, which is stated on the carton/blister after "EXP". 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 any medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Loperamide hydrochloride contains:

Each capsule contains 2 mg of Loperamide hydrochloride.

The other ingredients are:

Lactose, maize starch, talc, magnesium stearate, gelatin, colouring agents sunset yellow FCF (E110), erythrosine (E127), patent blue (E131), indigotine (E132) and titanium dioxide (E171) (see "Loperamide contains Lactose and colouring agent Sunset Yellow FCF (E110)" in section 2).

What Loperamide looks like and the contents of the pack:

Loperamide are grey-dark green coloured, hard, gelatin size 3 capsules, filled with homogenous white to off white powder.

Loperamide is available in:

Loperamide is available in packs of 30 or 60 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder & Manufacturer

Tillomed Laboratories Limited
220 Butterfield, Great Marlings
Luton, LU2 8DL, United Kingdom

Legal category:
Prescription Only Medicine (POM)

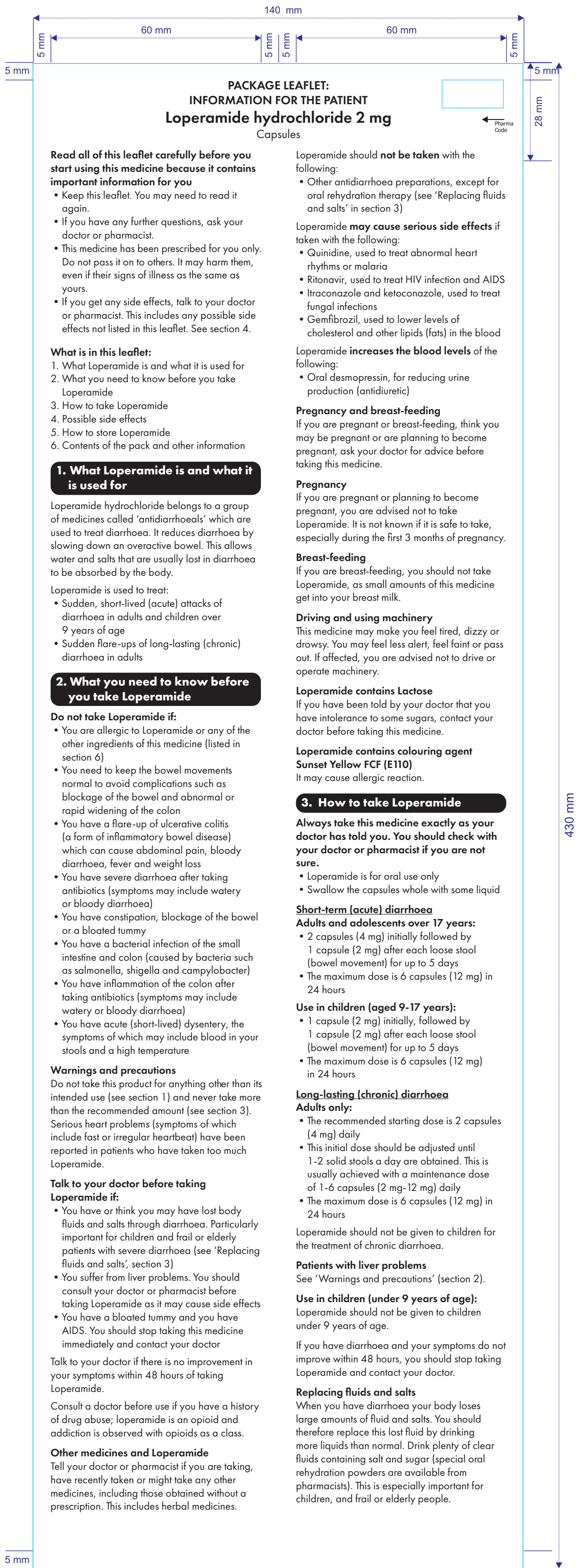
Product Licence Number:
PL 11311/0516

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| Product Name | Loperamide 2 mg Capsules | Sap code : | TBA | Reference Artwork | CC22-147 202812 |
| Packaging Material | Package leaflet (POM) | Reason of change : | TW140325 (.com) | Proof 1 | 19/08/2024 |
| Size : Strip Size | | Country : | UK | | |
| Size : Foil Width | | Pack Size : | All | | |
| Size : PI - Open Size | 110 mm (W) x 460 mm (L) | Barcode No. : | NA | | |
| Size : PI - Folded Size | 110 x 30 mm | Pharmacode : | TBA | | |
| Size : Carton/Label | | No. of colours : | 1 | | |
| PM Style/Type : | | Min. Font Size : | 9 points (Reg text) | | |
| Remark (If any) : | Printed leaflet for Loperamide HCL 2mg Capsule (Tillomed Laboratories/UK) (Pharma code: TBA) Specification: 40GSM Bible Paper | | | | |

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| Product Name | Loperamide 2 mg Capsules | Sap code : | ----- | Reference Artwork | 510521419GB02 |
| Packaging Material | Package leaflet (POM) | Reason of change : | Editorial changes | Proof 1 | 20.08.2024 |
| Size : Strip Size | | Country : | UK | Proof 2 | |
| Size : Foil Width | | Pack Size : | All | | |
| Size : Pl - Open Size | 140 mm (W) x 430 mm (L) | Barcode No. : | NA | | |
| Size : Pl - Folded Size | 110 x 28 mm | Pharmacode : | ----- | | |
| Size : Carton/Label | | No. of colours : | 1 | | |
| PM Style/Type : | | Min. Font Size : | 9 points (Reg text) | | |
| Remark (If any) : | Emcure assembly | | | | |

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