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## Information for the user

(New Logo)

# Diarrhoea Relief 2 mg Hard Capsules (Loperamide Hydrochloride)

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

This medicine is available without prescription to treat a minor condition. However, you still need to take it carefully to get the best results from it.

- Keep this leaflet, you may need to read it again
- Ask your pharmacist if you need more information or advice

## What this medicine is for

This medicine contains Loperamide Hydrochloride which belongs to a group of medicines called antidiarrhoeals, which act to relieve the symptoms of sudden, **short term diarrhoea** ("acute" diarrhoea). It works by making the stools ("poo") more solid and less frequent.

It can be used to relieve short term diarrhoea in adults and children aged 12 years and over.

## Before you take this medicine

This medicine can be taken by adults and children of 12 years and over. However, diarrhoea is a common symptom of a number of serious stomach and bowel conditions and therefore some people should not take this medicine or should seek the advice of their pharmacist or doctor first.

### **X Do not take:**

- **If you are allergic** to loperamide or to any of the ingredients in this medicine (see "What is in this medicine")
- **If you are having a flare up of an inflammatory bowel condition**, such as ulcerative colitis
- **If you have** very smelly stools, blood or pus in your stools, stomach pain, or a fever
- **If you have dysentery** (a disease caused by eating and drinking contaminated food and water) – you may have a fever and blood in your stools
- **If you have severe diarrhoea after taking antibiotics**
- **If you have a swollen stomach**
- **If you are constipated**, or have any condition which may cause constipation or where constipation should be avoided
- **If you have** paralysis (non movement) of the bowel muscles, or an obstruction of the bowel
- **If you have an intolerance to some sugars**, unless your doctor tells you to (this medicine contains lactose)
- **If you are pregnant or breastfeeding**, unless your doctor tells you to

### **! Talk to your pharmacist or doctor:**

- If you have liver problems
- If you have AIDS (you may be more likely to experience some of the side effects - if your stomach becomes swollen stop taking the capsules and talk to your doctor)
- If you are frail or elderly (you may need additional rehydration therapy, see "Other important information")
- Do not take this product for anything other than its intended use (see "What this medicine is for") and never take more than the recommended amount (see "How to take this medicine"). Serious heart problems (symptoms of which include fast or irregular heartbeat) have been

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reported in patients who have taken too much loperamide, the active ingredient in this medicine.

## Other important information

Diarrhoea is a common symptom of a number of serious stomach and bowel conditions. If your diarrhoea continues or keeps coming back talk to your doctor.

**Dehydration** may be a complication of diarrhoea, as large amounts of fluid are lost in the stools. This medicine acts only to make the stools more solid and less frequent and does not replace lost fluids. Therefore it is important to drink more fluid than usual.

When your body loses fluid, the amount of salts (electrolytes) in your body may also change and this can cause a condition called electrolyte imbalance. To help balance the fluid and salt levels in your body to the right levels your pharmacist may recommend that you also take a “rehydration treatment” if you have diarrhoea, especially if you are elderly.

**Driving and using machines:** Diarrhoea or this medicine may cause people to feel tired, sleepy or dizzy. You should not drive or use machines, until you are sure you are not affected.

**Information about some of the ingredients in this medicine:** The colour ponceau 4R (E124) in this medicine may cause allergic reactions.

## If you take other medicines

Before you take these capsules, make sure that you tell your pharmacist about ANY other medicines you might be using at the same time, particularly the following:

- Ritonavir (used to treat HIV)
- Quinidine (for heart rhythm problems), gemfibrozil (for reducing blood fat levels)
- Itraconazole, ketoconazole (for fungal infections)
- Desmopressin (for treating excessive urination or bed wetting)
- Other medicines for diarrhoea, constipation, or for other stomach and bowel conditions

If you are unsure about interactions with any other medicines, talk to your pharmacist. This includes medicines prescribed by your doctor and medicine you have bought for yourself, including herbal and homeopathic remedies.

## ✓ How to take this medicine

Check the foil is not broken before use. If it is, do not take that capsule.

Age	How many	How often
Adults and children of 12 years and over	Two capsules to start with. After that, take one capsule.	After each loose bowel movement. <b>Don't take more than 5 capsules</b> in any 24 hours.

Swallow each capsule with water.

Do not give to children under 12 years.

Do not take more than the amount recommended above.

If your short term diarrhoea does not go away within 24 hours talk to your doctor (see “Other important information”).

- ! If you take too many capsules:** If you have taken too many Boots Pharmaceuticals Diarrhoea Relief 2 mg Hard capsules, immediately contact a doctor or hospital for advice. Symptoms may include: increased heart rate, irregular heartbeat, changes to your heartbeat

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(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 this medicine than adults. If a child takes too much or shows any of the above symptoms, call a doctor immediately. Take your medicine and this leaflet with you.

## **Possible side effects**

Most people will not have problems, but some may get some.

**! If you get any of these serious side effects, stop taking the capsules. See a doctor at once:**

- Difficulty in breathing, swelling of the face, neck, tongue or throat (severe allergic reactions)  
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

**If you get any of the following side effects see your pharmacist or doctor.**

Common side effects:

(less than 1 in every 10 people are affected)

- Headache, dizziness
- Feeling sick, constipation, wind

Uncommon side effects:

(less than 1 in every 100 people are affected)

- Dry mouth, being sick, indigestion, stomach discomfort, stomach or upper abdominal pain
- Feeling very sleepy or wanting to sleep
- Skin rash

Rare side effects:

(less than 1 in every 1000 people are affected)

- Obstruction of the bowel, dilation of the bowel, paralysis (non movement) of the bowel muscles which may stop bowel movements
- Swelling of the stomach and abdomen
- Allergic skin reactions such as itchy, red, raised rash (which can sometimes be severe and include peeling, swelling, blistering and lesions of the skin)
- General feeling of tiredness, loss or decreased levels of consciousness, lack of coordination, lack of response to stimulation
- Difficulty focussing
- Difficulty passing urine, tensing of the muscles

**If any side effect becomes severe, or you notice any side effect not listed here, please tell your pharmacist or doctor.**

## **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 HPRA Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **How to store this medicine**

Do not store above 30°C.

Store in the original package, in order to protect from moisture.

Keep this medicine in a safe place out of the sight and reach of children, preferably in a

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locked cupboard.

Use by the date on the end flap of the carton or on the foil edge. After this date return any unused product to your nearest pharmacy for safe disposal.

## **What is in this medicine**

Each capsule contains Loperamide Hydrochloride 2 mg, which is the active ingredient.

As well as the active ingredient, the hard capsules also contain lactose monohydrate, pregelatinised maize starch, magnesium stearate. The capsule shell contains gelatin, ponceau 4R (E124), indigo carmine (E132), titanium dioxide (E171), yellow and black iron oxides (E172), printing ink (containing black iron oxide (E172), shellac, propylene glycol).

The pack contains 12 or 18 hard capsules. The capsules have an opaque green cap printed "0611" in black ink and an opaque grey body. Not all pack sizes may be marketed.

## **Who makes this medicine**

Manufactured for the Marketing Authorisation holder Taw Pharma (Ireland) Ltd 104 Lower Baggot Street, Dublin 2, Dublin, Ireland, D02 Y940 by Famar AVE Anthoussa Attiki 15349 Greece

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If you would like any further information about this medicine, please contact The Boots Company PLC Nottingham NG2 3AA, UK

## **Other formats**

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

1890 708091 (ROI only)

And ask for Boots Medical Information.

Please be ready to give the following information:

Product name: Diarrhoea Relief 2 mg Hard Capsules

Reference number: PA 23081/002/001