

## Information for the user



### Diarrhoea Relief Instant-Melts 2 mg Orodispersible Tablets (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

#### 1. 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 of 12 years and over. It can also be used by adults of 18 years and over, who have **irritable bowel syndrome** (IBS), which has been previously diagnosed by a doctor, to relieve short term diarrhoea associated with it.

#### 2. 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 a child under 12 years of age**
- **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 acute 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 you have a condition which may cause constipation or where constipation should be avoided such as if you are severely dehydrated
- **If you have** paralysis (non movement) of the bowel muscles, or an obstruction of the bowel
- **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 tablets and talk to your doctor)
- If you have IBS but have not had this condition previously diagnosed by a doctor
- If you have IBS, which has previously been diagnosed by a doctor, but you notice any of the following symptoms:
  - If you are 40 years or over and it is some time since your last IBS attack, or if the symptoms are different this time
  - If you have recently passed blood from the bowel
  - If you have severe constipation
  - If you are feeling sick or being sick
  - If you have lost your appetite or lost weight, especially if losing weight without trying
  - If you have difficulty or pain passing urine
  - If you have a fever
  - If you have recently travelled abroad

## **Warnings and precautions**

Consult with a doctor if you have a history of drug abuse. Loperamide is a type of opioid that acts directly on the gut when used as recommended but can cause other opioid effects when misused at high doses. Addiction is observed with opioids as a class. Abuse and misuse of loperamide, the active ingredient in this medicine, have been reported. 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 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:** 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.

## **If you take other medicines**

Before you take these tablets, 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)
- Itraconazole, ketoconazole (used to treat fungal infections)
- Gemfibrozil (for lowering levels of fat in the blood)
- 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.

This medicine contains less than 1 mmol sodium (23mg) per tablet, that is to say essentially “sodium free”.

### 3. How to take this medicine

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

With dry hands take the tablet from the foil and place immediately on the tongue.

The tablets, which are “melt in the mouth” peppermint flavoured tablets, are designed to be placed on the tongue and allowed to completely disintegrate before swallowing. The tablets will normally disintegrate in the mouth in contact with saliva, therefore water or other liquids are not normally needed in order to take the tablets.

However, you may need to drink more fluid than usual when you have diarrhoea as fluids may be lost in the stools (see “Other important information”).

Age	What for	How many	How often
Adults and children of 12 years and over	<b>Short term diarrhoea</b>	2 tablets to start with. After that, take 1 tablet after each loose bowel movement.	<b>Do not take more than 6 tablets in any 24 hours.</b> <b>Don't take for more than 48 hours.</b>
Adults only (18 years and over)	Diarrhoea associated with <b>irritable bowel syndrome</b> , which has been diagnosed by a doctor	2 tablets to start with. After that, take 1 tablet as needed until stools become solid.	<b>Do not take more than 6 tablets in any 24 hours.</b> <b>Don't take for more than 48 hours for each attack of diarrhoea.</b>

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 48 hours talk to your doctor.

If you need to take this medicine for repeated attacks of diarrhoea associated with IBS for more than 14 days, or if you notice new symptoms, or symptoms worsen, talk to your doctor.

**! If you take too many tablets:** If you have taken too much of this medicine, 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 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.

#### **4. 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 tablets. 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 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
- Burning sensation of the tongue
- 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
- Fatigue
- Constriction of the pupil

#### **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](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store this medicine**

Do not store above 25°C.

The tablets should be stored in the original packaging, in order to protect from moisture. Keep this medicine in a safe place out of the sight and reach of children, preferably in a locked cupboard.

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

## **6. What is in this medicine**

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

As well as the active ingredient, the tablets also contain citric acid anhydrous, croscarmellose sodium, crospovidone, magnesium stearate, mannitol, colloidal silica anhydrous, colloidal silica hydrated, pregelatinised starch, sucralose, peppermint flavour.

This pack contains 6 or 12 white, round flat tablets.

## **Who makes this medicine**

Manufactured for The Boots Company PLC Nottingham NG2 3AA by Galpharm International Ltd., Elmhirst Park, Middle Field Road, Barnsley, South Yorkshire, S75 4LS, UK.

Marketing Authorisation held by Galpharm Healthcare Ltd., Wrafton, Braunton, Devon, EX33 2DL, UK.

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

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