

Package leaflet: Information for the patient



Diarrhoea Relief Instant-Melts
2 mg Orodispersible Tablets
(Loperamide Hydrochloride)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor, or pharmacist or nurse have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 24 hours.

What is in this leaflet :

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

1. What this medicine is and what it is used for

This medicine contains Loperamide Hydrochloride which is an anti-diarrhoeal medicine which helps to stop diarrhoea by making the stools more solid and less frequent.

This medicine is used for the treatment of sudden short-lived (acute) attacks of diarrhoea in adults and adolescents 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.

Please note that these tablets relieve the symptoms of diarrhoea and should not be used as a substitute for rehydration treatment.

2. What do you need to know before you take this medicine

Do not take this medicine if:

- you suffer from colitis (inflammation of the colon) or any other inflammatory bowel disease associated with the use of broad-spectrum antibiotics
- you have bacterial enterocolitis caused by invasive organisms including Salmonella, Shigella and Campylobacter. (symptoms may include watery or bloody diarrhoea).
- you have the feeling of an inflated abdomen, disruption of the normal propulsive ability of the bowel (ileus) and/or constipation particularly in severely dehydrated children.
- inhibition of intestinal motility is to be avoided due to the possible risk of disruption of the normal propulsive ability of the bowel, abnormal swelling of the large bowel, abnormal swelling of the large bowel in the context of systemic toxicity and certain poisonings in particular.
- you are allergic to loperamide or to any other ingredient in this medicine.
- it is for a child under 12 years of age.
- you have acute dysentery, the symptoms of which may include blood in your stools and a high temperature.

Warnings and precautions

Check with your doctor before taking this medicine:

- If you have AIDS and your stomach becomes swollen. Stop taking the tablets immediately and talk to your doctor.
- If you have liver problems.
- If you have diarrhoea that lasts for more than 48 hours.
- If you have severe and/or persistent diarrhoea as your body loses more fluid, sugars and salts than normal.
- If you have chronic diarrhoea

Only take Boots Diarrhoea Relief Instant-Melts 2 mg Orodispersible Tablets to treat acute episodes of diarrhoea associated with Irritable Bowel Syndrome if your doctor has previously diagnosed IBS.

If any of the following now apply, do not use the product without first consulting your doctor, even if you know you have IBS:

- If you are aged 40 or over and it is some time since your last IBS attack
- If you are aged 40 or over and your IBS symptoms are different this time
- If you have recently passed blood from the bowel
- If you suffer from severe constipation
- If you are feeling sick or vomiting
- If you have lost your appetite or lost weight
- If you have difficulty or pain passing urine
- If you have a fever
- If you have recently travelled abroad. Consult your doctor if you develop new symptoms, if your symptoms worsen, or your symptoms have not improved over two weeks.

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).

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.

Abuse and misuse of loperamide, the active ingredient in this medicine, have been reported.

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 medicines and this medicine

Talk to your pharmacist before taking this medicine if you are taking any other medicines, particularly the following:

- ritonavir (used to treat HIV),
- quinidine (used to treat abnormal heart rhythms or malaria),
- oral desmopressin (used to treat excessive urination),
- itraconazole or ketoconazole (used to treat fungal infections),
- gemfibrozil (used to treat high cholesterol).

Pregnancy and breast-feeding

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

Driving and using machines

This medicine may make you feel dizzy, tired or sleepy. You may feel less alert, feel faint or pass out. If you are affected do not drive or use machines.

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

3. How to take the medicine

The orodispersible tablets should be placed on the tongue. The tablet will dissolve and is to be swallowed with saliva. No liquid intake is needed for the orodispersible tablet.

FOR: Acute diarrhoea.	
Age:	How many tablets:
Adults and adolescents of 12 years and over.	2 tablets to be taken initially, followed by 1 tablet after each loose motion.
How often to take:	
<ul style="list-style-type: none"> • Do not give to children under 12 years of age. • Do not take more than 6 tablets in any 24 hours. • Do not take for more than 48 hours. • If the symptoms persist for more than 48 hours consult your doctor. 	
<ul style="list-style-type: none"> • DO NOT EXCEED THE STATED DOSE. 	

Further information overleaf

FOR: Acute diarrhoea associated with irritable bowel syndrome, which has been diagnosed by a doctor.

Age:	How many tablets:
Adults only (18 years and over).	2 tablets to be taken initially, followed by 1 tablet after each loose motion (or as advised by your doctor).

How often to take:

- Do not give to children and adolescents under 18 years of age.
- Do not take more than 6 tablets in any 24 hours.
- You can use this medicine for up to 2 weeks for repeated attacks, but do not take for any one attack lasting longer than 48 hours.
- If you need to take this medicine for more than 14 days, or if you notice new symptoms, or your symptoms get worse, talk to your doctor.

- **DO NOT EXCEED THE STATED DOSE.**

Rehydration sachets are available separately.

If you take more of this medicine than you should

If you have taken too much of this medicine, immediately contact a doctor or hospital for advice. Symptoms may include: increased heart rate, abnormal or irregular heartbeat, cardiac arrest, fainting, changes to your heartbeat (these symptoms can have potentially serious, life-threatening consequences), severely reduced consciousness, excessive narrowing of the pupils, constipation, disruption of the normal propulsive ability of the bowel, muscle tension, uncoordinated movements, drowsiness, inability to completely empty the bladder, 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. Patients with liver problems may also react more strongly to large amounts of this medicine.

If you forget to take this medicine

You should only take this medicine as you need it, 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.**

4. Possible side effects

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

Serious side effects

Stop taking this medicine and see your doctor immediately if you experience any of these serious side effects:

- Allergic reactions including unexplained sudden, severe allergic reaction with breathing difficulty, swelling, lightheadedness, fast heartbeat, sweating and loss of consciousness
- Skin rashes, which may be severe and include blistering or peeling skin such as a lifethreatening reaction with flu-like symptoms and painful rash affecting the skin, mouth, eyes and genitals (Stevens-Johnson Syndrome), life-threatening reaction with flu-like effects and blistering in the skin, mouth, eyes and genital (toxic epidermal necrolysis), swelling of skin or mucous membranes, face, tongue and throat causing breathing difficulties (angioedema)
- Loss of consciousness or state of severely reduced consciousness

Other serious side effects are:

- Paralytic ileus, a disruption of the normal propulsive ability of the bowel due to paralysis
- Abnormal swelling of the large bowel in the context of systemic toxicity (toxic megacolon)
- Sudden inflammation of the pancreas causing severe pain in the belly and back (acute pancreatitis)

Common: (may affect up to 1 in 10 people)

- Feeling sick, constipation or wind
- Headache.

Uncommon: (may affect up to 1 in 100 people)

- Dizziness or drowsiness
- Abdominal pain or discomfort
- Abdominal pain upper
- Dry mouth
- Vomiting
- Indigestion
- Rash

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

- Uncoordinated movements
- Muscle tension
- Disruption of the normal propulsive ability of the bowel (ileus)
- Abnormal swelling of the large bowel (megacolon)
- Itchiness or hives
- Stomach pain or swollen stomach
- Inability to completely empty the bladder (urinary retention)
- Miosis (excessive narrowing of the pupils of the eye)
- Tiredness
- Erythema multiforme (skin reaction with redness that usually is mild and goes away in a few weeks)
- Burning sensation of the tongue

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 this medicine

Do not store above 25°C. Keep the container in the original carton in order to protect from light. Do not use the tablets after the expiry date shown on the pack. The expiry date refers to the last day of that month

Keep out of the sight and reach of children.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What is in this medicine:

The active ingredient in the tablets is: Loperamide Hydrochloride 2 mg.

The other ingredients in the tablets are: Mannitol, Pregelatinised Starch, Croscopovidone, Croscarmellose Sodium, Colloidal Anhydrous Silica, Colloidal Hydrated Silica, Magnesium Stearate, Citric Acid, Peppermint Flavour and Sucralose.

Contents of the pack:

This pack contains 6 Orodispersible tablets.

Marketing Authorisation Holder: Galpharm Healthcare Ltd, Wrafton, Braunton, Devon, EX33 2DL, United Kingdom.

Manufacturer:

Omega Pharma Ltd, DMC 02, County Way, Barnsley, South Yorkshire, S70 2AG, United Kingdom

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