

Numark Diarrhoea Relief Instants 2mg Orodispersible Tablets

Loperamide Hydrochloride
PATIENT INFORMATION LEAFLET

Read 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.

IN THIS LEAFLET:

1. What this medicine is for
2. Before you take the medicine
3. How to take the medicine
4. Possible side effects
5. Storing the medicine
6. Further information

1 WHAT THIS MEDICINE IS FOR

Numark Diarrhoea Relief Instants 2mg Orodispersible Tablets contain 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 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.

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

2 BEFORE YOU TAKE THE MEDICINE

Do not take this medicine if:

- you are allergic to loperamide or any other ingredient in this medicine,
- you are a child under 12 years of age (or under 18 for an IBS patient),
- you have severe diarrhoea after taking antibiotics,
- you are having a flare up of an inflammatory bowel condition, such as ulcerative colitis,
- you are constipated, or your stomach appears swollen (especially in children with severe dehydration),
- you have acute dysentery, the symptoms of which may include blood in your stools and a high temperature,
- you are pregnant or breast-feeding, unless instructed by your doctor.

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 diarrhoea as your body loses more fluid, sugars and salts than normal.
- If you develop a bowel obstruction stop taking the tablets and consult 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 new symptoms:
 - o you are 40 years or over and it is some time since your last IBS attack, or if the symptoms are different this time
 - o you have recently passed blood in the bowel
 - o you have severe constipation
 - o you are feeling sick or being sick
 - o you have lost your appetite or lost weight
 - o you have difficulty or pain passing urine
 - o you have a fever
 - o you have recently travelled abroad.

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, the active ingredient in this medicine.

If you take other medicines:

- 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).

If you are unsure about any of the medicines you are taking, talk to your pharmacist.

Further information overleaf

3 HOW TO TAKE THE MEDICINE

FOR: Acute diarrhoea.

Age:	How many tablets:
Adults and children of 12 years and over.	2 tablets to be taken initially, followed by 1 tablet after each loose motion.

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

FOR: 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).

- Do not give to children and young adults 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 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, 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.

4 POSSIBLE SIDE EFFECTS

Most people take the tablets without any problems, but as with all medicines, side effects may occur occasionally.

Stop taking the medicine and contact your doctor immediately if you notice:

- **Rare:** (affects less than 1 in 1,000 but 1 or more in 10,000 people)
- Allergic reactions including unexplained

- wheezing, shortness of breath, or swelling of the face and throat.
- Skin rashes, which may be severe and include blistering or peeling skin.
- Loss of consciousness or reduced level of consciousness (passing out, feeling faint or less alert), uncoordinated movements.

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

If you experience any of the following stop taking the medicine and talk to your doctor:

Rarely: (between 1 in 10,000 and 1 in 1000 people are affected)

- Itchiness or hives
- Constriction of the pupil
- Difficulty passing water (urine)
- A swollen stomach, a burning sensation in the mouth, lips or tongue
- Fatigue.

Uncommonly: (between 1 in 1000 and 1 in 100 people are affected)

- Tiredness, drowsiness
- Stomach pains, vomiting, indigestion and heartburn, dry mouth.

Commonly: (between 1 in 100 and 1 in 10 people are affected)

- Headache, dizziness
- Nausea (feeling sick), constipation, flatulence (wind).

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. By reporting side effects you can help provide more information on the safety of this medicine.

5 STORING THE 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.

Keep out of the sight and reach of children.

6 FURTHER 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 Maize Starch, Croscopovidone, Croscarmellose Sodium, Colloidal Anhydrous Silica, Colloidal Hydrated Silica, Magnesium Stearate, Citric Acid Anhydrous, Peppermint Flavour and Sucralose.

Contents of the pack:

This pack contains 6 or 12 Orodispersible tablets.

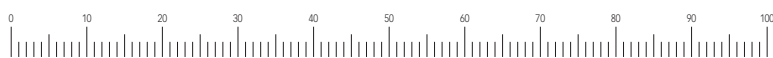
Marketing Authorisation Holder:

Galpharm Healthcare Ltd., Wrafton, Braunton, Devon, EX33 2DL, United Kingdom.

Manufacturer:

Galpharm International Ltd., Elmthorpe Park, Middle Field Road, Barnsley, South Yorkshire, S75 4LS, United Kingdom.

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JOB INFORMATION		JOB SPECIFICATION	
Product Name: Numark Diarrhoea Relief Instants 2mg Orodispersible Tablets	Project Name: Loperamide PRAC updates	Dimensions: 130 x 210mm	Supplier: Sharon Bio-Medicine
Customer: Numark	HUB No.: 11078	Profile No.: L146G	Printer: TBC
Market: UK	Component No.: H1G00ETJ1	Pharmacode: TBC	Print Process: Litho
Component: Leaflet	Customer Code: N/A	EAN Code: N/A	Substrate: White paper
Pack Size: 6	Supplier Code: TBC	MAIN BODY TEXT	
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Print Colours: BLACK		Non-print Colours: KEYLINE	

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