Package leaflet: Information for the user

Loperamide hydrochloride 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 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. 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 2 days.
- fluid by drinking more liquid than What is in this leaflet

What Loperamide hydrochloride 2 mg

- Orodispersible Tablets are and what they are used for 2. What you need to know before you
- take Loperamide hydrochloride 2 mg Orodispersible Tablets 3. How to take Loperamide hydrochloride
- 2 mg Orodispersible Tablets 4. Possible side effects
- How to store Loperamide hydrochloride
- 2 mg Orodispersible Tablets Contents of the pack and other
- information 1. What Loperamide hydrochloride

and what they are used for Loperamide hydrochloride is used to treat

two types of diarrhoea. The two types have different age limits. Short-term diarrhoea

2 mg Orodispersible Tablets are

For adults and children aged 12 and

- To treat attacks that last up to 48 hours.
- If your attack lasts longer than 48 hours, talk to your doctor.
- IBS diarrhoea For adults and young people aged

- 18 and over who have been diagnosed with IBS (Irritable Bowel Syndrome). To treat attacks that last up to 48 hours.
- You can use this medicine for up to 2 weeks for repeated attacks, but if
- any one attack lasts continuously for longer than 48 hours, talk to your doctor. The tablets contain loperamide hydrochloride, a substance that helps

reduce diarrhoea by slowing down an

overactive bowel. This allows water and

salts that are usually lost in diarrhoea to be absorbed by the body. 2. What you need to know before you take Loperamide hydrochloride 2 mg Orodispersible Tablets

Warnings for everyone This medicine is suitable for most people, but a few people should not use it:

Do not take Loperamide hydrochloride 2 mg Orodispersible Tablets if:

If you have ever had a bad reaction to any of the ingredients.

- If it is for a child aged under 12 (or under 18 for an IBS patient).
- If you nave severe diarrnoea after taking antibiotics.
- If you are having a flare-up of an inflammatory bowel condition like ulcerative colitis. If you are constipated, or your
- stomach appears swollen (especially in children with severe dehydration). If you have acute dysentery, the symptoms of which may include **blood**

in your stools and a high temperature.

Loperamide hydrochloride. Warnings and precautions Talk to your doctor before taking Loperamide

hydrochloride 2 mg Orodispersible Tablets:

If any of these applies to you, talk to a doctor or pharmacist and do not take

If you have **AIDS** and your **stomach** becomes swollen, stop taking the

sugars.

tablets immediately and contact your If you suffer from liver disease.

- If you have diarrhoea that lasts for more than 48 hours. If you have been told by your doctor that you have an intolerance to some
- salts than normal. Other medicines and Loperamide hydrochloride 2 mg Orodispersible **Tablets**

Tell your doctor or pharmacist if you are

If you have severe diarrhoea as your body loses more fluid, sugars and

taking, have recently taken or might take any other medicines, including: 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).

your pharmacist.

If you are unsure about any of the medicines you are taking, show the bottle or pack to

If any of these applies to you (now or in the past), talk to a doctor or pharmacist.

Pregnancy and breast-feeding

If you are pregnant, think you are pregnant or planning a pregnancy: ask your doctor or pharmacist for advice before taking this medicine.

- If you are breast-feeding do not take this medicine. Small amounts may get into your milk. Talk to your doctor about a suitable treatment.
- **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're affected do not drive, cycle or use machines. Special warnings about this medicine

Your body can lose large amounts of fluids and salts when you have

diarrhoea. You need to replace the

usual. Ask your pharmacist about rehydration therapy to replace lost salts. This is especially important for children, and frail or older people. Consult with a doctor if you have a history of drug abuse.

- Loperamide hydrochloride 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
- 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

hydrochloride have been reported.

heartbeat) have been reported in patients who have taken too much loperamide hydrochloride. Loperamide hydrochloride 2 mg **Orodispersible Tablets contain Sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'. This medicine contains 5 mg aspartame in each orodispersible tablet. Aspartame

is a source of phenylalanine. It may be

harmful if you have phenylketonuria

(PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly. This medicine contains saccharose (a type of sugar). If you have been told by your doctor that you have an intolerance

before taking this medicinal product. Do not take this medicine: If you are aged under 18.

to some sugars, contact your doctor

If you are aged 40 or over and it is some time since your last IBS attack.

Talk to your doctor first:

- 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.
- ir you have difficulty or pain passing urine. If you have a fever.
- If you have recently travelled abroad. If any of these applies to you, talk to

your doctor before taking Loperamide

hydrochloride.

How to take Loperamide hydrochloride 2 mg Orodispersible **Tablets**

your doctor or pharmacist if you are not Check the tables below to see how much medicine to take. Swallow the correct number of tablets

described in this leaflet or as your doctor or pharmacist has told you. Check with

Always take this medicine exactly as

whole with a drink of water. For oral

- Do not use more than the dose shown in the tables. The tablets are **not for long-term**
- Short-term diarrhoea

Take two tablets

Adults and children aged 12 and over to start treatment. Take one tablet

treatment.

Age

		bowel movement.
•	Do not take for attacks lasting longer	
	than 48 hours.	
•	Do not take more	than six tablets in
	a 24-hour period.	
•	Replace lost fluid	by drinking more
	liquid than usual.	, 3

How long to take Loperamide hydrochloride for short-term diarrhoea You can use this medicine for up to

48 hours. If your attack lasts longer than

48 hours, stop taking this medicine and

Not for children aged under 12.

IBS diarrhoea Age Dose Adults aged 18 Take **two tablets** to start treatment. and over Take **one tablet** after each loose

bowel movement

liquid than usual.

aged under 18.

talk to your doctor.

	(or as advised by your doctor).	
•	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. Do not take more than six tablets in a 24-hour period. Replace lost fluid by drinking more	

Talk to your doctor and stop taking this medicine: If you have been using this medicine

continuously for 48 hours.

Not for children and young people

- If you develop new IBS symptoms.
 - If your IBS symptoms get worse.
 - If your IBS symptoms have not improved after 2 weeks.

How long to take Loperamide hydrochloride for IBS diarrhoea You can use this medicine for up to 2 weeks for repeated attacks of IBS diarrhoea. But if any one attack lasts for longer than 48 hours, stop taking this medicine and talk to your doctor.

If anyone takes too much of this medicine

If you have taken too many tablets,

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. If you forget to take the medicine You should only take this medicine as you

need it, following the dosage instructions

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

above carefully.

everybody gets them. Get medical help at once Rare: (may affect up to 1 in 1,000 people)

Like all medicines, this medicine can

cause side effects, although not

Allergic reactions including unexplained wheezing, shortness of

- breath, passing out or swelling of 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), muscle stiffness and uncoordinated movements. 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.

Talk to a doctor as soon as possible Uncommon: (may affect up to 1 in 100

Itchiness or hives. Stomach pain or swollen stomach.

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

people)

- Difficulties passing water. Severe constipation.
- Miosis (narrowing of the pupils of the eye).
- Hypertonia (muscle tension). Coordination abnormality (uncoordinated movements).

Other effects that may occur **Common:** (may affect up to 1 in 10 people)

If you notice any of the above, stop using the medicine and talk to a doctor.

Feeling sick, constipation or wind. Headache.

- **Uncommon:** (may affect up to 1 in 100 people) Dizziness or drowsiness.
- Vomiting, indigestion. Dry mouth.

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

If you get any side effects, talk to your

Reporting of side effects

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 Loperamide hydrochloride 2 mg Orodispersible

Keep this medicine out of the sight and reach of children.

date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not use this medicine after the expiry

Store below 25°C. Do not throw away any medicine 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 Loperamide hydrochloride 2 mg **Orodispersible Tablets contain** The active substance is loperamide hydrochloride. Each orodispersible tablet contains 2 mg loperamide hydrochloride.

The other excipients are croscarmellose sodium, aspartame E951, fruit flavour (contains acacia gum E414, sugar (saccharose), maltodextrin (potato), triacetin, propylene glycol), banana flavour (contains Maize maltodextrin),

magnesium stearate, mannitol.

Orodispersible Tablets looks like and contents of the pack Round white to off white orodispersible tablets with a diameter of approximately

What Loperamide hydrochloride 2 mg

Loperamide hydrochloride 2 mg Orodispersible Tablets are available in packs of 6 and 12 orodispersible tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder Milpharm Limited Ares Block

Odyssey Business Park West End Road Ruislip HA4 6QD United Kingdom

Manufacturer Tiofarma B.V.

mineral salts.

by a healthy diet.

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HEALTH EDUCATION RECOMMENDATION

This leaflet was last revised in 10/2024.

Diarrhoea causes a loss of fluids and

This medicine treats the symptomatic treatment of acute diarrhoea in adults and children from 12 years of age, but does

not dispense with rehydration, accompanied

It is therefore necessary to drink abundantly sweetened drinks (fruit juices) and salty broths to compensate for these losses. Avoid milk, green vegetables, raw

vegetables, fruits and spices until the diarrhoea disappears.