

Package leaflet: Information for the user

GALPHARM DIARRHOEA RELIEF 2MG CAPSULES

(Loperamide Hydrochloride)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for 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 24 hours.

What is in this leaflet:

- 1. What this medicine is and what it is used for**
- 2. What 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

Galpharm Diarrhoea Relief 2mg Capsules 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.

If your attack lasts longer than 24 hours, **talk to your doctor.**

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

2 What 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
- you have bacterial enterocolitis (symptoms may include watery or bloody diarrhoea)
- you have a swollen stomach or tummy, and/or constipation
- you are allergic to any of the ingredients listed in Section 6
- you are suffering from dysentery with blood in your stools and a high temperature

- it is for a child aged under 12.

Talk to your doctor or pharmacist before taking this medicine if:

- you suffer from liver or kidney problems, including difficulty in urinating
- you have severe and persistent diarrhoea and vomiting
- you have diarrhoea that lasts for more than 24 hours
- you suffer from severe diarrhoea as your body loses more fluid, sugars and salts than normal.

If you have AIDS and your stomach becomes swollen, stop taking the capsules immediately and contact your doctor.

Other medicines and this medicine

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines including medicines obtained without prescription and especially:

- 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 or 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** 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 are affected do not drive or use machines.

This medicine contains lactose

The capsules contain lactose; if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3 How to take this medicine

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Adults, the elderly and children over 12 years

How to take: The capsules should be swallowed whole with a drink of water.

Dose and how often to take: After the first loose stool (bowel motion) take 2 capsules with water. After each further loose stool, take 1 capsule.

Further information overleaf

- Rehydration sachets are available separately.
- **Do not give to children under 12 years of age.**
- Do not take more than 6 capsules in any 24 hours.
- Do not take the capsules for more than 24 hours unless advised by a doctor.
- If symptoms persist for more than 24 hours consult your doctor.
- Replace lost fluid by drinking more liquid than usual.
- **DO NOT EXCEED THE STATED DOSE.**

If you take more medicine than you should

If you have taken more medicine, contact your doctor or nearest Accident and Emergency department taking this leaflet with you.

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

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

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

- 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), uncoordinated movements.

Other side effects

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.

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

- Itchiness or hives

- Stomach pain or swollen stomach
- Difficulties in passing water
- Miosis (narrowing of the pupils of the eye)
- Tiredness.

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 How to store this medicine

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

Do not store above 25°C. Store in the original container.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of the month.

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

6 Contents of the pack and other information

What this medicine contains:

The active ingredient in the capsules is: Loperamide Hydrochloride 2mg per capsule.

The other ingredients in the capsules are: Lactose, Maize Starch, Talc, Magnesium Stearate, Gelatin, Quinoline Yellow (E104), Erythrosine (E127), Patent Blue (E131) and Titanium Dioxide (E171).

What this medicine looks like and contents of the pack: Galpharm Diarrhoea Relief 2mg Capsules are blue and grey capsules, available in a pack of 6 capsules.

Marketing Authorisation Holder:

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

Manufacturer:

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

This leaflet was last revised in September 2016.