

Galpharm Diarrhoea Relief 2mg Capsules

(Loperamide Hydrochloride)

PATIENT INFORMATION LEAFLET

Read this leaflet carefully 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.
- You should contact a doctor if your symptoms worsen or do not improve within 24 hours.

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

Galpharm Diarrhoea Relief 2mg Capsules are blue and grey in colour and 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.

Please note that these capsules 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 suffer from colitis (inflammation of the colon) or any other inflammatory bowel disease.
- You have a swollen stomach or tummy, and/or constipation.
- You are allergic to any of the ingredients listed in Section 6.

- You are pregnant or breast-feeding (unless instructed by your doctor).
- You are suffering from dysentery with blood in your stools and a high temperature.

Check with your doctor before taking this medicine if:

- You suffer from liver or kidney problems, including difficulty in urinating.
- You have severe and persistent diarrhoea and vomiting.

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

Important information about some of the ingredients of this medicine:

- 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 THE MEDICINE

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.

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

IF YOU TAKE TOO MUCH: If you take more capsules than you should, tell your doctor or pharmacist.

Further information overleaf.

4 POSSIBLE SIDE EFFECTS

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

Very rarely: (affects less than 1 in 10,000 people)

Allergic reaction:

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

- skin rashes or other signs of allergic reaction such as itching, swelling of the lips, tongue or throat, or difficulty in breathing
- Skin rashes which may be severe and include blistering or peeling skin.

Other side effects which may occur are:

Very rarely: (affects less than 1 in 10,000 people)

- Stomach pains, a swollen stomach, nausea, vomiting, constipation, flatulence (wind), indigestion and heartburn
- Tiredness and dizziness
- Dry mouth
- Difficulty urinating

If you experience any side effect which is troublesome, or not listed in this leaflet, stop taking the medicine and tell your pharmacist or doctor.

5 STORING THE MEDICINE

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

Do not use the capsules after the expiry date shown on the pack.

Keep all medicines out of the reach and sight of children.

6 FURTHER INFORMATION

What is in this medicine:

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

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).

Contents of the pack:

The pack contains 6 Capsules.

Marketing Authorisation Holder:

Galpharm Healthcare Ltd, Upper Cliffe Road, Dodworth Business Park, Dodworth, South Yorkshire S75 3SP

Manufacturer:

Galpharm International Ltd, Upper Cliffe Road, Dodworth Business Park, Dodworth, South Yorkshire S75 3SP

Leaflet revised: March 2012

4002767

000000