

## **PROMIDE**

(LOPERAMIDE CAPSULES BP 2 MG)

### **PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER**

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#### **1. WHAT LOPERAMIDE CAPSULE IS AND WHAT IT IS USED FOR**

Loperamide hydrochloride is the active ingredient of Loperamide Capsule. The Capsules are available in one strength. Loperamide is one of a group of medicines called "antidiarrhoeals" which are used to treat diarrhoea.

Loperamide 2 mg Capsule are used to treat sudden short-lived (acute) attacks of diarrhoea in adults and children aged 9 years and over and long-lasting (chronic) diarrhoea in adults.

The Capsule help reduce diarrhoea by slowing down an overactive bowel, which helps the body to absorb water and salts from this organ, making the stools more solid and less frequent.

#### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LOPERAMIDE CAPSULE**

Do not use Loperamide Capsule

- if you are allergic to loperamide hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- if you have severe diarrhea 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 (particularly in children with severe dehydration)
- if you have acute dysentery, the symptoms of which may include blood in your stools and a high temperature.

Do not give this medicine to a child under 9 years old.

Do not use this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Loperamide Capsule.

Warnings and precautions

Talk to your doctor or pharmacist before taking Loperamide Capsule

- if you have AIDS and your stomach becomes swollen, stop taking the Capsule immediately and contact your doctor - if you suffer from liver problems
- if you have severe diarrhoea as your body loses more fluid, sugars and salts than normal.
- if you have diarrhoea that lasts for more than 48 hours.

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

Special warnings: -

Loperamide only treats the symptoms of diarrhoea. When you have diarrhoea, your body can lose large amounts of fluids and salts. You will need to replace the fluid by drinking more liquid than usual. This is especially important for children. Ask your pharmacist about special powders (known as oral rehydration therapy) which replace fluids and salts lost during diarrhoea. The prevention of fluid depletion (dehydration) is of particular importance in infants, children and frail and elderly people with acute diarrhoea.

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 Loperamide Tablet.

Other medicines and Loperamide Capsule

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. In particular, tell your doctor or pharmacist if you are taking any of the following:

- ritonavir (used to treat HIV)
- quinidine (used to treat abnormal heart rhythms or malaria)
- itraconazole, ketoconazole (used to treat fungal infections)
- gemfibrozil (used to reduce levels of cholesterol)
- oral desmopressin (used to treat excessive urination)
- other drugs that slow down or speed up movement in the gut

Pregnancy and breast-feeding

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

Do not take this medicine if you are breast-feeding as small amounts may get into your milk. Talk to your doctor about suitable treatment.

Driving and using machines Do not drive if you feel dizzy, tired or sleepy after taking this medicine. You may also lose consciousness, feel faint or less alert. If affected do not drive or operate machinery.

Loperamide Capsule contains lactose If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

### **3. HOW TO TAKE LOPERAMIDE CAPSULE**

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The dose of Loperamide Capsule that you will need will depend on whether your diarrhoea is a sudden, short lived attack (acute) or a long-lasting condition (chronic).

- Take this medicine by mouth.
- Swallow the correct number of Capsule whole with a drink of water.
- The score line is only there to help you break the Capsule if you have difficulty swallowing it whole.

#### **Short-lived (acute) diarrhea**

Adults and children over 12 years:

- Take two Capsule to begin with and then one Capsule after each episode of diarrhoea for up to 5 days. - Never take more than 8 Capsule in any 24 hour period.

Children aged 9-12 years:

- Take one Capsule 4 times daily until diarrhoea is controlled or for up to 5 days.
- Never take more than this dose.

Children aged under 9 years old:

This medicine should not be given to children under 9 years old. Other pharmaceutical forms/strengths (e.g. syrup) are available for children aged 4 years and over.

If your symptoms are not getting better within 2 days of taking your first dose of this medicine, you should see your doctor again, who may want to examine you to further check on the cause of the diarrhoea.

#### **Long-lasting (chronic) diarrhea**

Adults only:

- Your doctor will tell you how much Loperamide Capsule to take.
- The initial dose will probably be between two and four Capsule per day taken in divided doses, but will depend on each individual's needs. When your doctor is satisfied that you are receiving the daily dose that best suits you, he or she will then probably suggest that you take your Capsule twice a day.
- Never take more than 8 Capsule in any 24 hour period.

If you take more Loperamide Capsule than you should

If you have taken too many Loperamide Capsule, 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, reduction in size of

the pupils in the eye (miosis), constipation and a condition where the bowel does not work properly (ileus). Children react more strongly to large amounts of Loperamide than adults. If a child takes too much or shows any of the above symptoms, call a doctor immediately.

If you forget to take Loperamide Capsule

- You should only take this medicine as required 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 to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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#### **4. POSSIBLE SIDE EFFECTS**

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

Stop using Loperamide Capsule and tell your doctor straight away if you notice or suspect any of the following. You may need urgent medical treatment.

- Sudden swelling of the face lips, or throat. Hives (also known as nettle rash or urticaria). Severe irritation, reddening or blistering of your skin. These may be signs of a severe allergic reaction
- Blistering of your skin, mouth, eyes or genitals
- Stomach pain or severe swollen stomach
- Severe constipation
- Loss of consciousness or reduced level of consciousness (feeling faint)

Tell your doctor if you notice any of the following side effects while using Loperamide Capsule:

Common side effects (may affect up to 1 in 10 people)

- Headache - Feeling sick (nausea)
- Constipation
- Wind

Uncommon side effects (may affect up to 1 in 100 people)

- Feeling sleepy or drowsy
  - Dry mouth
  - Being sick (vomiting), indigestion (dyspepsia)
  - Rash
  - Abdominal pain or discomfort
  - Feeling dizzy
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Rare side effects (affects fewer than 1 in 1000 patients)

- Tiny pupils
- Itchy skin
- Difficulty passing water
- Feeling tired
- Problems with co-ordination
- Unusually stiff muscles causing poor control of movement
- Burning, tingling mouth (glossodynia)

Some of the listed side effects may be due to the diarrhoea, such as discomfort around the middle, feeling sick or being sick, dry mouth, feeling tired, drowsy or dizzy and wind.

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## 5. HOW TO STORE LOPERAMIDE CAPSULE

Keep out of the sight and reach of children.

Do not use capsule after the expiry date which is printed after 'Exp' on the carton.

Do not store above 30°C. Keep the Capsule in their original pack.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. Further information

Sr.No.	Excipients	Specification
1.	Maize Starch	BP
2.	Lactose	BP
3.	Purified Talc	BP
4.	Colloidal Anhydrous Silica	BP
5.	Magnesium Stearate	BP
6.	E.H.G. Capsule Size :2 Green/Gray	IHS

### Marketing authorization holder

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