

FDA PIL Template.  
**Pelodium Capsules**  
(Loperamide Hydrochloride Capsules USP 2mg)

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

**Pelodium Capsules-**  
(Loperamide Hydrochloride Capsules USP 2mg)

**Read all of this leaflet carefully before you start taking using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

**In this leaflet:**

1. What **Pelodium 2 mg Hard Gelatin Capsule**. is and what it is used for
2. Before you take and use **Pelodium 2 mg Hard Gelatin Capsule**
3. How to take and use **Pelodium 2 mg Hard Gelatin Capsule**
4. Possible side effects
5. How to store **Pelodium 2 mg Hard Gelatin Capsule**.
6. Further information

1. **WHAT Pelodium 2 mg Hard Gelatin Capsule IS AND WHAT IT IS USED FOR**

**For** the symptomatic treatment of acute diarrhoea, in adults and children 12 years and over.

**For** the symptomatic treatment of acute episodes of diarrhoea associated with Irritable Bowel Syndrome in adults aged 18 years and over following initial diagnosis by a doctor.

2. **BEFORE YOU TAKE and USE Pelodium 2 mg Hard Gelatin Capsule.**

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

**Do not take Pelodium 2 mg Hard Gelatin Capsule:**

- If you are allergic to loperamide or any of the other ingredients of this medicine (listed in section 6).
- If it is for a child aged **under 12** (or under 18 for an IBS patient).
- If you have **severe Diarrhoea** 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**.

If any of these applies to you, **talk to your doctor or pharmacist and do not take Pelodium 2 mg Hard Gelatin Capsule**

**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

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**Pelodium Capsules**  
(Loperamide Hydrochloride Capsules USP 2mg)

of which include fast or irregular heartbeat) have been reported in patients who have taken too much loperamide, the active ingredient in **Pelodium 2 mg Hard Gelatin Capsule**

**Talk to your doctor or pharmacist before taking Pelodium 2 mg Hard Gelatin Capsule**

- If you have **AIDS** and your **stomach becomes swollen**, stop taking the capsules immediately and contact your doctor.
- 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 sugars**.
- If you have **severe Diarrhoea** as your body loses more fluid, sugars and salts than normal.
- If you are taking 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**).

If you are unsure about any of the medicines you are taking, show the bottle or pack to your pharmacist. If any of these applies to you (now or in the past), talk to a doctor or pharmacist.

**Special warnings about this medicine**

Your body can lose large amounts of fluids and salts when you have Diarrhoea. You need to replace the fluid by drinking more liquid than usual. Ask your pharmacist about **rehydration therapy** to replace lost salts. **This is especially important for children, and frail or older people.**

**Extra warnings for IBS patients** Use only if your doctor has previously diagnosed IBS.

Check the following:

**Do not take use Pelodium 2 mg Hard Gelatin Capsule.**

- If you are aged under 18.

**Talk to your doctor first:**

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

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**Pelodium Capsules**  
(Loperamide Hydrochloride Capsules USP 2mg)

- If 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 **Pelodium 2 mg Hard Gelatin Capsule**

Pregnancy and 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're affected do not drive, cycle or use machines.

**Pelodium 2 mg Hard Gelatin Capsule**

This product 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.

3. **HOW TO TAKE USE Pelodium 2 mg Hard Gelatin Capsule**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

**Check the tables below to see how much medicine to take.**

. Swallow the correct number of capsules whole with a drink of water. For oral use only.

. Do not use more than the dose shown in the tables

The capsules are not for **long-term treatment**

**Short-term Diarrhoea.**

Age	Dose
<b>Adults and children aged 12 and over</b>	Take <b>two capsules</b> to start treatment. Take <b>one capsule</b> after each loose bowel movement.
• Do not take for attacks lasting <b>longer than 48 hours.</b> • Do not take more than <b>six capsules</b> in a 24-hour period.	
• Replace lost fluid by drinking more liquid than usual. • Not for children aged under 12.	

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**Pelodium Capsules**  
(Loperamide Hydrochloride Capsules USP 2mg)

**How long to take Pelodium 2 mg Hard Gelatin Capsules for short-term Diarrhoea**

You can use this medicine for up to 48 hours. If your attack lasts longer than 48 hours, stop taking Pelodium 2 mg Hard Gelatin Capsules and talk to your doctor.

**IBS Diarrhoea**

Age	Dose
Adults aged 18 and over	Take <b>two capsules</b> to start treatment. Take <b>one capsule</b> after each loose bowel movement (or as advised by your doctor).
<ul style="list-style-type: none"><li>• You can use this medicine <b>for up to 2 weeks</b> for repeated attacks, but do not take for any one attack lasting <b>longer than 48 hours</b></li><li>• Do not take more than <b>six capsules</b> in a 24-hour period.</li></ul>	
<ul style="list-style-type: none"><li>• Replace lost fluid by drinking more liquid than usual.</li><li>• Not for children and young people aged under 18.</li></ul>	

**Talk to your doctor and stop taking this medicine:**

- If you have been using this medicine **continuously for 48 hours**
- 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 Pelodium 2 mg Hard Gelatin Capsules 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 Pelodium 2 mg Hard Gelatin Capsules and **talk to your doctor.**

**If you take more Pelodium 2 mg Hard Gelatin Capsules than you should**

If you have taken too many **Pelodium 2 mg Hard Gelatin 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.

Children react more strongly to large amounts of **Pelodium 2 mg Hard Gelatin Capsules** 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 2mg Hard Capsules**

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).

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**Pelodium Capsules**  
(Loperamide Hydrochloride Capsules USP 2mg)

**Do not** take a double dose to make up for a forgotten dose.

**4. POSSIBLE SIDE EFFECTS**

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

Most are usually mild.

**Get medical help at once**

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

- 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.

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 people)

- Itchiness or hives.
- Stomach pain or swollen stomach. **Rare:** (may affect up to 1 in 1,000 people)
- Difficulties passing water.
- Severe constipation.
- Miosis (narrowing of the pupils of the eye).

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

**Other effects that may occur 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.
- Vomiting, indigestion.
- Dry mouth.

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

- 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.

**5. HOW TO STORE Pelodium 2 mg Hard Gelatin Capsule.**

Keep out of the sight and reach of children.

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**Pelodium Capsules**  
(Loperamide Hydrochloride Capsules USP 2mg)

Store in the original container in order to protect from moisture.

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

Do not throw away any medicines 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. FURTHER INFORMATION**

### **What Pelodium 2 mg Hard Gelatin Capsule contains**

- The active substance(s) is Loperamide Hydrochloride Capsules USP 2mg
- The other ingredient(s) are as excipients –

Maize Starch	BP
Lactose	BP
Dibasic calcium phosphate	BP
Sodium Laurel Sulphate	BP
Colloidal Silicon Dioxide (Aerosil)	BP
Sodium Starch Glycollate	BP
Magnesium Stearate	BP

### **What Pelodium 2 mg Hard Gelatin Capsule looks like and contents of the pack.**

**Appearance of Capsule** - Size '4' hard gelatin capsule with "Green" coloured cap & "Gray" coloured body, filled with white colour Powder.

**Content of Pack-** 10 capsules packed in one Blister. Such 10 blister packed in a carton along with its package insert.

### **Manufacturer**

MAXHEAL LABORATORIES PVT LTD  
PLOT NO. - 2-7/80-85, SURSEZ,  
G.I.D.C SACHIN, SURAT  
GUJARAT-394230.  
INDIA

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**Date of publication or revision**  
**Not Applicable**