

Diarrhoea Relief 2 mg Capsules

Loperamide

Bell's Healthcare**PACKAGE LEAFLET: INFORMATION FOR THE USER**

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

Bell's Healthcare Diarrhoea Relief 2 mg Capsules will be referred to as Diarrhoea Relief 2 mg Capsules throughout this leaflet.

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Diarrhoea Relief 2 mg Capsules are and what they are used for.
2. What you need to know before you take Diarrhoea Relief 2 mg Capsules.
3. How to take Diarrhoea Relief 2 mg Capsules.
4. Possible side effects.
5. How to store Diarrhoea Relief 2 mg Capsules.
6. Contents of the pack and other information.

1. What Diarrhoea Relief 2 mg Capsules are and what they are used for

Diarrhoea Relief 2 mg Capsules are used to treat two types of diarrhoea. The two types have different age limits.

Short-term diarrhoea

- For adults and children aged 12 and over.
- 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 capsules 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 Diarrhoea Relief 2 mg Capsules

This medicine is suitable for most people, but a few people should not use it: Do not take Diarrhoea Relief 2 mg Capsules:

- 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 apply to you, **talk to your doctor or pharmacist and do not take Diarrhoea Relief 2 mg Capsules.**

Warnings and Precautions

Talk to your doctor or pharmacist before taking Diarrhoea Relief 2 mg Capsules:

- 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.**

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.

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. Consult with a doctor if you have a history of drug abuse.

Loperamide 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, the active ingredient in Diarrhoea Relief 2 mg Capsules, have been reported. 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 2 mg Capsules.

Diarrhoea Relief 2 mg Capsules contain lactose

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.

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

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

Check the following:

Do not take this medicine:

- 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;
- 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 Diarrhoea Relief 2 mg Capsules.

3. How to take Diarrhoea Relief 2 mg Capsules

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
Adults and children aged 12 and over	Take two capsules to start treatment. Take one capsule after each loose bowel movement.
<ul style="list-style-type: none"> Do not take for attacks lasting longer than 48 hours. Do not take more than six capsules in a 24-hour period. 	
<ul style="list-style-type: none"> Replace lost fluid by drinking more liquid than usual. Not for children aged under 12. 	

How long to take Diarrhoea Relief 2 mg 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 Diarrhoea Relief 2 mg Capsules and **talk to your doctor**.

IBS diarrhoea

Age	Dose
Adults and children aged 18 and over	Take two capsules to start treatment. Take one capsule (or as advised by your doctor) after each loose bowel movement.
<ul style="list-style-type: none"> 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 6 capsules in a 24-hour period. 	
Replace lost fluid by drinking more liquid than usual. Not for children and young people aged under 18.	

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 Diarrhoea Relief 2 mg 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 Diarrhoea Relief 2 mg Capsules and talk to your doctor.

If you take more Diarrhoea Relief 2 mg Capsules than you should

If you have taken too many Diarrhoea Relief 2 mg Capsules, 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 Diarrhoea Relief 2 mg 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 Diarrhoea Relief 2 mg 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). Do not take a double 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 the 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.

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

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 people

- Dizziness or drowsiness;
- Vomiting, indigestion;
- Dry mouth;
- Itchiness or hives;
- Stomach pain or swollen stomach.

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.

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 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 Diarrhoea Relief 2 mg Capsules

Keep this medicine out of the sight and reach of children.
Store in the original package.
Do not use this medicine after the expiry date which is stated on the outside packaging (EXP).
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. Contents of the pack and other information**What Diarrhoea Relief 2 mg Capsules contain**

The active substance is Loperamide hydrochloride.
Each hard gelatin capsule contains 2 mg Loperamide hydrochloride.
The other ingredients are maize starch, lactose, talc and magnesium stearate.
The capsule shell contains gelatin, titanium dioxide (E171), quinoline yellow (E104), carmoisine (E122), sunset yellow (E110) and patent blue V (E131).
The printing ink contains shellac, dimeticone, titanium dioxide (E171) and propylene glycol (E1520) (see section 2).

What Diarrhoea Relief 2 mg Capsules look like and contents of the pack.

The medicine is enclosed in a green and dark grey capsule. The pack contains 6 capsules.

Marketing Authorisation Holder and Manufacturer

Relonchem Limited,
Cheshire House,
Gorse Lane,
Widnes, Cheshire, WA8 0RP, UK.

Product Licence Number:
PL 20395/0289

GSL

This leaflet was last revised in March 2024.

D27-0069