

Lopedium®

loperamide (as hydrochloride) capsules

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Lopedium.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

WHAT LOPEDIUM IS USED FOR

This medicine is used to treat diarrhoea.

It contains the active ingredient loperamide hydrochloride.

It works by making the stool more solid and less frequent. It does this by normalising muscle contractions of the intestine. This allows the bowel time to absorb water and produce a more solid stool.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

BEFORE YOU TAKE LOPEDIUM

When you must not take it

Do not take this medicine if you have an allergy to:

- loperamide (as hydrochloride), the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description
- any other similar medicines.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine if you have any of the following medical conditions:

- constipation or have to avoid becoming constipated
- severe diarrhoea with blood in the stools
- severe diarrhoea and fever (for example after taking antibiotics).

Do not breastfeed if you are taking this medicine.

The active ingredient in Lopedium passes into the breast milk and there is a possibility that your baby may be affected.

Do not give this medicine to a child under the age of 12 years.

Safety and effectiveness in children younger than 12 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your pharmacist or doctor if you have or have had any of the following medical conditions:

- liver problems
- kidney problems
- glaucoma (pressure in the eye) or bladder problems
- AIDS (Acquired Immune Deficiency Syndrome)
- regularly drink a lot of alcohol.

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor or pharmacist can discuss with you the risks and benefits involved.

If you have not told your doctor or pharmacist about any of the above, tell him/her before you start taking Lopedium.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Lopedium may interfere with each other. These include:

- medicines used to treat depression
- sleeping tablets or medicines to treat anxiety and nervousness
- medicines that slow down the action of the stomach and intestines.

These medicines may be affected by Lopedium, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

HOW TO TAKE LOPEDIUM

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

Adults and Children over 12 years 2 capsules initially, followed by 1 capsule after each loose unformed stool as required. Do not take more than 8 capsules in a 24 hours period.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Lopedium. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include constipation, nausea, muscle stiffness, uncoordinated movements, drowsiness or weak breathing.

WHILE YOU ARE TAKING LOPEDIUM

Things you must do

If there is no improvement after taking Lopedium for 48 hours, do not continue to take it and consult your doctor or pharmacist.

Drink plenty of fluids, to prevent dehydration.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Lopedium.

Things you must not do

Do not drink alcohol while taking Lopedium.

Do not take Lopedium to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how Lopedium affects you.

Tiredness, drowsiness and dizziness are symptoms of diarrhoea.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Lopedium.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- constipation
- nausea
- stomach pain
- dry mouth
- headache
- weakness, tiredness, giddiness
- difficulty passing urine
- flatulence.

These are mild side effects of the medicine, and are short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- skin rash and itching
- vomiting
- blurred vision.

The above list includes serious side effects that may require medical attention.

If any of the following happen, stop taking Lopedium, and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- asthma, wheezing or shortness of breath
- sudden or severe blisters, itching, skin rash, hives
- flaking or peeling of the skin.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

AFTER TAKING LOPEDIUM

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store Lopedium or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

Lopedium 2mg - grey/ dark green capsules.

Available in blisters of 8 capsules.

Ingredients

Active ingredients:

- Lopedium 2mg - 2mg loperamide hydrochloride.

Inactive ingredient:

- lactose
- maize starch
- purified talc
- magnesium stearate
- gelatin
- iron oxide black
- iron oxide yellow
- titanium dioxide
- patent blue.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Lopedium is supplied in Australia by:

Sandoz Pty Ltd

ABN 60 075 449 553

19 Harris St

Pymont NSW 2009

Tel: 1800 634 500

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Australian Register Numbers

Lopedium 2mg capsules: AUST R 98878 (blister)