

NEW ZEALAND CONSUMER MEDICINE INFORMATION

DIAMIDE

Loperamide hydrochloride Capsules 2 mg



What is in this leaflet

Please read this leaflet carefully before you start taking DIAMIDE.

This leaflet answers some common questions about DIAMIDE.

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 or pharmacist has weighed the risks of you taking DIAMIDE 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 DIAMIDE is used for

DIAMIDE is used to treat patients with sudden (acute) or long-lasting (chronic) diarrhoea. It is also used to treat diarrhoea in people with an ileostomy (part of the intestines removed by surgery).

DIAMIDE contains the active ingredient loperamide hydrochloride.

It works by increasing gut transit time so that food takes longer to pass through the gastrointestinal tract. This allows the bowel time to absorb water and produce a more solid stool.

Your doctor or pharmacist may have recommended this medicine for another reason.

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

This medicine is available from your pharmacy in limited quantities.

Before you take DIAMIDE

When you must not take it

Do not take DIAMIDE if:

- you are constipated
- you have severe diarrhoea with blood in the stools and fever
- you have ulcerative colitis (a type of inflammatory bowel disease)
- you have an infection of the bowel.

Do not take DIAMIDE if you have an allergy to:

- any medicine containing loperamide hydrochloride
- any of the ingredients listed at the end of this leaflet.

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 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 or pharmacist.

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

- liver problems
- AIDS
- glaucoma
- bowel or urinary problems.

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant or are breast-feeding. 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 them before you start taking DIAMIDE.

Taking other medicines

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

You should also tell any health professional who is prescribing a new medication for you that you are taking DIAMIDE.

Some medicines may interfere with DIAMIDE. These include:

- monoamine oxidase inhibitors (type of antidepressant), such as Tranylcypromine

- tranquilisers
- alcohol
- quinidine
- ritonavir
- itraconazole
- gemfibrozil
- ketoconazole
- desmopressin.

These medicines may be affected by DIAMIDE 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 DIAMIDE

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 on the box, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how much DIAMIDE you need to take each day. It is important that you take DIAMIDE as directed by them. Do not take more than the recommended dose.

In adults, including children over 12 years of age, with sudden (acute) diarrhoea, the usual dosage of DIAMIDE is 2 capsules, followed by 1 capsule after every subsequent loose stool.

In adults, including children over 12 years of age, with long-lasting (chronic) diarrhoea, the initial dosage of DIAMIDE is 2 capsules daily. This initial dosage will be adjusted until 1 to 2 solid stools a day are obtained.

The total daily dose in both instances should not exceed 8 capsules.

How to take it

Swallow the capsules whole with a full glass of water.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it

For sudden (acute) diarrhoea, see your doctor if diarrhoea persists for more than 48 hours.

For long-lasting (chronic) diarrhoea, continue taking your medicine for as long as your doctor tells you.

If you forget to take it

If you forget a dose, skip the dose you missed and take the next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking DIAMIDE

Things you must do

If there is no improvement after taking DIAMIDE for 48 hours, tell your doctor.

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take DIAMIDE 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.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

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

This medicine may cause dizziness, tiredness and drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, symptoms such as dizziness may be worse.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to Accident and Emergency at your nearest hospital, if you think that

you or anyone else may have taken too much DIAMIDE. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the pack of DIAMIDE with you if you can.

Symptoms of an overdose may include impaired consciousness, poor control of movements, tiredness, constricted pupils, shallow breathing, constipation, difficulties to pass urine, stomach pain, bloating, cramps, flatulence, nausea, vomiting, disorders of heart rhythm or chest pain.

Side effects

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

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.

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
- stomach pain, bloating or cramps
- flatulence
- nausea, vomiting
- tiredness, drowsiness, dizziness
- headache
- dry mouth
- impaired consciousness
- poor control of movements
- constricted pupils
- difficulties to pass urine.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

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

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

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

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

Other side effects not listed above may also occur in some people. Tell your doctor or pharmacist if you notice any other effects.

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

After taking DIAMIDE

Storage

Keep your capsules in the pack until it is time to take them.

If you take the capsules out of the pack they may not keep well.

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

Do not store DIAMIDE 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

DIAMIDE capsules are half purple and half dark green capsules. Each capsule is marked with "LOPERAMIDE 2" on the green half with white ink.

DIAMIDE is available in blister packs containing 10 or 20 capsules.

Ingredients

Active ingredient:

DIAMIDE contains 2 mg of loperamide hydrochloride as the active ingredient.

Inactive ingredients:

It also contains:

- lactose monohydrate
- maize starch
- magnesium stearate
- gelatin
- shellac
- isopropyl alcohol
- ammonium hydroxide
- n-butyl alcohol
- propylene glycol
- simethicone
- ethanol
- polyvinyl pyrrolidone
- sodium hydroxide
- titanium dioxide
- erythrosine
- indigo carmine
- black iron oxide
- quinoline yellow.

This medicine does not contain gluten.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

DIAMIDE is supplied in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland
NEW ZEALAND

Telephone: 0800 168 169

Date of Preparation

31 January 2020
(Based on datasheet dated 30
January 2020)