NEW ZEALAND CONSUMER MEDICINE INFORMATION

NŌDIA

Loperamide hydrochloride 2 mg tablets

What is in this leaflet?

This leaflet answers some common questions about NŌDIA. 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 NÖDIA against the benefits it can offer you.

If you have any concerns about using NŌDIA, ask your doctor or pharmacist.

Keep this leaflet with your medicine. You may want to read it again.

What NŌDIA is used for and how it works

NŌDIA tablets contain loperamide hydrochloride, a medicine that makes the stools more solid and less frequent. It does this by restoring the muscle contractions of the intestine to normal. This allows the bowel time to absorb water and produce a more solid stool.

NŌDIA is used to treat sudden (acute) diarrhoea.

NŌDIA is also prescribed by doctors to treat long-lasting (chronic) diarrhoea or diarrhoea in patients who have had part of their intestines removed by surgery (intestinal resection).

Before you take NŌDIA

When you must not take it

Do not take NŌDIA if:

- you have an allergy to loperamide hydrochloride or any of the other ingredients listed at the end of this leaflet
- you are constipated or have to avoid being constipated
- you have severe diarrhoea with blood in the stools or a fever
- your doctor has diagnosed an inflammation of the lower bowel such as ulcerative colitis or antibiotic associated pseudomembranous colitis
- you are breast-feeding

 the packaging is torn or shows signs of tampering.

Do not take NŌDIA after the expiry or useby date printed on the pack. Medicines may not be effective if taken after their expiry date.

Do not give NŌDIA to children under the age of 12 years.

Before you take it

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

Also tell your doctor or pharmacist if you:

- are pregnant or are planning to become pregnant
- are breastfeeding.
- have or have ever had liver disease
- have kidney disease
- have AIDS (Acquired Immune Deficiency Syndrome)
- have glaucoma (high pressure in the eve)
- have bladder problems
- regularly drink a lot of alcohol.

Taking other medicines

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

In particular, tell your doctor or pharmacist if you are taking any of the following:

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

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking NŌDIA.

How to take NŌDIA

How much to take

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

Sudden (acute) diarrhoea

For adults and children over 12 years of age, the usual dose is 2 NÕDIA tablets initially, followed by 1 tablet after each loose unformed stool, as needed.

Your doctor or pharmacist may set a different dose for you.

Do not take more than 8 tablets in one day. Do not take NÕDIA for more than 24 hours without seeking advice from a healthcare practitioner.

NÕDIA will usually stop the symptoms of diarrhoea within 48 hours. If it does not, stop taking the medicine and see your doctor.

If you forget a dose

If you forget to take NÕDIA, just take the next dose when you remember or after your next unformed stool. Do not take a double dose to make up for the one you missed. If you are not sure what to do, check with your doctor or pharmacist.

If you have taken too much (overdose)

Immediately contact your doctor or the National Poisons Information Centre for advice, or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any NŌDIA by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the pack of NŌDIA with you, if you can.

National Poisons Information Centre telephone number is 0800 POISON or 0800 764 766. Keep this telephone number handy in case of an emergency.

If you take too much NÕDIA, you may have any of the following symptoms: impaired consciousness, constricted pupils, sleepiness, nausea and vomiting, constipation, difficulty passing urine, stomach pain, bloating, cramps, flatulence, weak breathing, muscle stiffness, unco-ordinated movements, disorders of heart rhythm or chest pain.

Children are more sensitive than adults to medicines such as NŌDIA. An accidental overdose is especially dangerous. Make sure NŌDIA is kept out of reach of children.

While you are taking NŌDIA

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking NŌDIA. If you are going to have surgery, tell the surgeon or anaesthetist that you are taking NŌDIA.

Tell your doctor or pharmacist that you are taking NŌDIA before you start any new medicine.

Tell your doctor if you develop a skin rash or hives, or you become pregnant while taking NŌDIA.

If you are going to have any blood tests, tell your doctor that you are taking NŌDIA.

Drink plenty of fluids to avoid dehydration. A drink prepared from an ENERLYTE sachet provides a convenient source of electrolytes and glucose to help prevent dehydration.

Alongside the use of NŌDIA, attention to personal hygiene is very important. Regular hand washing reduces the spread of the organisms causing the diarrhoea.

Ask your employer if your illness may put others in the workplace at risk.

If there is no improvement in your symptoms after taking NÕDIA for 48 hours, tell your doctor.

Things you must not do

Do not take more than 8 tablets in one day.

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

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

Having diarrhoea may put others around you at risk. Check with your employer, school or university if attendance is necessary.

Things to be careful of

Be careful driving or operating machinery until you know how NÕDIA 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.

Storage

Keep your NŌDIA tablets in the carton until it is time to take them.

Store NŌDIA tablets in a cool dry place where the temperature stays below 25°C. Avoid exposure to heat, light and moisture.

Do not store NŌDIA, or any other medicine, in the bathroom or near a sink. Do not leave medicines in the car or on window sills. Heat and dampness can destroy some medicines.

Keep all medicines where children cannot reach them. A locked cupboard at least 1.5 metres above the floor is a good place to store medicines.

Side effects

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

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

- nausea or vomiting
- constipation
- flatulence
- dry mouth or bad taste
- headache
- stomach pain or bloating
- difficulty passing urine
- tiredness
- drowsiness or dizziness

- poor control of movements
- constricted pupils

These are the more common side effects and are usually mild.

Tell your doctor immediately and do not take your next dose of NÕDIA if you experience:

- asthma, wheezing or shortness of breath
- swelling of the face, lips, or tongue which may cause difficulty in swallowing or breathing
- sudden or severe blisters, itching, skin rash, hives, flaking or peeling of the skin
- loss of or depressed level of consciousness
- upper abdominal pain, abdominal pain that radiates to the back, tender and swollen abdomen, fever, nausea, vomiting which may be symptoms of acute pancreatitis

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

Other side effects not listed above may also occur in some people. Tell your doctor or pharmacist as soon as possible if you feel unwell while you are taking NÕDIA or when you have finished the treatment

Do not be alarmed by this list of possible side effects. You may not experience any of them. Ask your doctor or pharmacist if you do not understand anything in this list.

After using NŌDIA

Disposal

If your doctor tells you to stop taking NÕDIA or if the tablets have passed the expiry date, ask your pharmacist what to do with the remaining medicine.

Product description

What NŌDIA tablets look like

NÕDIA 2mg tablets are small light-greencoloured, capsule-shaped tablets, plain on one side and with a break line on the other.

Each NŌDIA tablet contains the active ingredient, loperamide hydrochloride.

Each NŌDIA tablet also contains lactose, sugars, maize starch, sodium starch

glycollate, povidone, silicon dioxide, talc, magnesium stearate, food colours 133 and 104.

NŌDIA 2mg tablets are available in blister packs of 8 (General sale) and 16 tablets (Pharmacy only).

If you want to know more

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

Distributor

Distributed in New Zealand by: Multichem NZ Ltd Private Bag 93527, Takapuna, Auckland. Telephone: (09) 488 0330

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