

# Norimode Tablets

## (Loperamide Hydrochloride USP 2mg Tablets)

Please read this entire leaflet carefully before you use Norimode.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should 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 or pharmacist.

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### 1 What this medicine is and what it is used for

Norimode belongs to a group of medicines called 'antidiarrhoeals' which are used to treat diarrhoea.

Norimode is used to treat sudden, short-lived (acute) attacks of diarrhoea in adults and children over 9 years of age. It is also used to treat sudden flare-ups of long-lasting (chronic) diarrhoea in adults.

It reduces diarrhoea by slowing down an overactive bowel. It also helps the body to absorb more water and salts from the bowel.

### 2 Before you take

**Do not take Norimode if:**

- you are allergic to Loperamide or any of the other ingredients (see 'Important information about some of the ingredients', section 2 and 6)
- you need to keep the bowel movements normal to avoid complications such as blockage of the bowel and abnormal or rapid widening of the colon
- you have acute ulcerative colitis (a form of inflammatory bowel disease) which can cause abdominal pain, bloody diarrhoea, fever and weight loss
- you have constipation, blockage of the bowel or a bloated tummy (in particular, in children with severe dehydration)
- you have a bacterial infection of the small intestine and colon (caused by bacteria such as salmonella, shigella and campylobacter)
- you have inflammation of the colon after taking antibiotics (symptoms may include watery or bloody diarrhoea)
- you have dysentery, which may include blood in your stools and a high temperature

**Take special care if:**

- you have or think you may have lost body fluids and salts through diarrhoea. Particularly important for children and frail or elderly patients with severe diarrhoea (see 'Replacing fluids and salts', section 3)
- you have liver disease. You should consult your doctor or pharmacist before taking Norimode as it may cause side effects
- you have inflammatory bowel disease (inflammation of the intestines), which can cause abdominal pain and bloody diarrhoea
- you have a bloated tummy and you have AIDS. You should stop taking the capsules immediately and contact your doctor

If any of the above apply to you, please consult your doctor or pharmacist.

**Taking other medicines**

Norimode may interact with other medicines. If you are taking other medicines, including medicines

obtained without a prescription and you are unsure about taking Norimode, you should contact your doctor or pharmacist.

Norimode should **not be taken** with the following:

- Other antidiarrhoea preparations, except for oral rehydration therapy (see "Replacing fluids and salts" in section 3)

Norimode **may cause serious side effects** if taken with the following:

- Quinidine, for abnormal and increased heart rhythm
- Digoxin, for heart failure
- Ritonavir or Tipranavir, for HIV infection and AIDS
- Itraconazole and Ketoconazole, for fungal infections
- Gemfibrozil, used to lower levels of cholesterol and other lipids (fats) in the blood.

Norimode **increases the blood levels** of the following:

- Oral desmopressin, for reducing urine production (antidiuretic).

**Pregnancy and breast-feeding**

If you are pregnant or planning to become pregnant, you are advised not to take Norimode. It is not known if it is safe to take, especially during the first 3 months of pregnancy.

If you are breast-feeding, you should not take Norimode, as small amounts of this medicine get into your breast milk.

**Driving and using machinery**

This medicine may make you feel tired, dizzy or drowsy. If affected, you are advised not to drive or operate machinery.

**Important information about some of the ingredients of Norimode**

**Lactose:** If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

### 3 How to take

You should always take this medicine as prescribed by your doctor. Read and follow the instructions on the pharmacist's label. If you are not sure about anything, please ask your doctor or pharmacist.

- Norimode is for oral use only
- Swallow the tablets whole with some liquid

**Normal dosage**

**Acute diarrhoea**

**Adults:**

- 2 tablets (4mg) initially, followed by 1 tablet (2mg) after each loose stool for up to 5 days
- The usual dosage is 3 to 4 tablets (6 - 8mg) a day
- The maximum dose for adults is 8 tablets (16mg) in 24 hours

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**Children aged 9-17 years:**

- 1 tablet (2mg) initially, followed by 1 tablet (2mg) after each loose stool for up to 5 days
- The usual dosage is 3 to 4 capsules (6 - 8mg) a day
- The maximum dose for children is related to body weight (3 tablets per 20kg). but should not exceed 8 capsules (16mg) a day

**Children under 9 years:**

This medicine should **not** be given to children under 9 years.

Loperamide (active ingredient) **must not** be given to children under 2 years of age.

**Chronic diarrhoea****Adults only:**

- The initial dose is usually 2 tablets (4mg) a day
- The initial dose should be adjusted until 1 - 2 solid stools a day are obtained. This is usually achieved with a maintenance dose of 1 - 6 capsules (2mg - 12mg) daily
- The maximum dose for adults with chronic diarrhoea is 8 tablets (16mg) a day

**Elderly and patients with kidney problems:**

Same dose as for adults.

**Patients with liver problems**

See 'Take special care' (section 2)

**Children**

Norimode should not be given to children for the treatment of chronic diarrhoea

**Do not take Norimode for longer than 5 days.**

If you have acute diarrhoea and your symptoms do not improve within 48 hours, you should stop taking Norimode and contact your doctor.

**Replacing fluids and salts**

When you have diarrhoea your body loses large amounts of fluid and salts. In addition to your medicine, you should take more liquids which contain sugar and salts, than normal.

- Drink plenty of clear fluids containing salt and sugar (special oral rehydration powders are available from pharmacists), unsweetened fruits juices or clear soups
- Avoid excessive plain water
- Do not drink alcohol or milk
- Do not eat fruit, green vegetables or fatty foods
- Two or three days after symptoms have disappeared you may return to your normal diet

**If you take more Norimode than you should**

Contact your doctor or go to your nearest casualty department immediately. Take the carton and this leaflet with you, so that people will know what you have taken.

Symptoms of an overdose include:

Constipation, difficulty passing urine, feeling bloated, stupor, difficulty co-ordinating movements, pupils of the eyes become smaller, increased muscle tension, difficulty sleeping, breathing problems or abnormally slow breathing.

**If you forget to take Norimode**

Take it as soon as you remember. Never double up a dose to make up for the dose you have missed.

**4 Possible side effects**

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

**Stop taking your medicine and contact your doctor immediately or nearest hospital if you experience the following** (rare side effects):

- Bloating tummy and you have AIDS
- Allergic reactions such as swollen face, lips or eyelids and serious reactions such as passing out, difficulty breathing and dizziness
- Blistering of the skin, mouth, eyes and genitals (Stevens Johnson Syndrome or toxic epidermal necrolysis)

**Common side effects** (affect less than 1 in 10 people)

- Headache
- Constipation
- Feeling sick (nausea)
- Stomach wind (flatulence)

**Uncommon side effects** (affect less than 1 in 100 people)

- Dizziness
- Drowsiness
- Stomach pain or discomfort
- Dry mouth
- Being sick (vomiting)
- Indigestion
- Rash

**Rare side effects** (affect less than 1 in 1,000 people)

- Loss of consciousness
- Reduced ability to respond to stimulation (stupor) or reduced consciousness
- Abnormal increase in muscle tension
- Difficulty co-ordinating movement
- Pupils of the eyes become smaller
- Blockage of the bowel
- Enlargement of the large intestine, which may cause constipation, bloating and tenderness of the stomach or fever (megacolon or toxic megacolon)
- Painful or burning feeling of the tongue
- Bloating tummy
- Itchy rash (urticaria) or itching (pruritus)
- Difficulty in urinating (passing water)
- Tiredness

**If any of the side effects listed become serious or you notice any side effects not listed, please contact your doctor or pharmacist.**

**5 How to store**

Store out of reach and sight of children. Keep this medicine in a dry, cool place (below 25°C) away from the light.

Do not take after the expiry date, which is stated on the carton after EXP.

**6 Further information****What Norimode Tablets contain:****Active ingredient:**

Loperamide Hydrochloride USP 2mg

**Other ingredients:**

Ludipress, consisting of lactose monohydrate 94% and polyvinylpyrrolidone 6% and magnesium stearate.

(see 'Important information about some of the ingredients', section 2, page 2)

**What Norimode Tablets look like and the contents of the pack**

Norimode tablets are round, white, biconvex tablets marked "T3" on one side and marked with a line on the other side.

The pack contains 30 tablets.

**Marketing Authorisation Holder & Manufacturer**

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**Product Licence Number**

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