

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Nilemdo® 180 mg film-coated tablets (bempedoic acid)

The name of your medicine is Nilemdo® 180 mg film-coated tablets but will be referred to as Nilemdo throughout the remainder of this leaflet.

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Nilemdo is and what it is used for
2. What you need to know before you take Nilemdo
3. How to take Nilemdo
4. Possible side effects
5. How to store Nilemdo
6. Contents of the pack and other information

1. WHAT NILEMDO IS AND WHAT IT IS USED FOR

What Nilemdo is and how it works

Nilemdo is a medicine that lowers levels of 'bad' cholesterol (also called "LDL-cholesterol"), a type of fat, in the blood. Nilemdo also can help reduce cardiovascular risk through lowering the levels of bad cholesterol.

Nilemdo contains the active substance bempedoic acid, which is inactive until it enters the liver where it is changed to its active form. Bempedoic acid decreases the production of cholesterol in the liver and increases the removal of LDL-cholesterol from the blood by blocking an enzyme (ATP citrate lyase) needed for the production of cholesterol.

What Nilemdo is used for

- Adults with primary hypercholesterolaemia or mixed dyslipidaemia, which are conditions that cause a high cholesterol level in the blood. It is given in addition to a cholesterol-lowering diet.
- Adults with high cholesterol levels in their blood who already have cardiovascular disease or have other conditions that put them at a higher risk of cardiovascular events.

Nilemdo is given:

- if you have been using a statin (such as simvastatin, a commonly used medicine that treats high cholesterol) and this does not lower your LDL-cholesterol sufficiently;
- alone or together with other cholesterol-lowering medicines when statins are not tolerated or cannot be used.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NILEMDO

Do not take Nilemdo:

- if you are allergic to bempedoic acid or any of the other ingredients of this medicine (listed in section 6);
- if you are pregnant;
- if you are breast-feeding;
- if you take more than 40 mg of simvastatin daily (another medicine used to lower cholesterol).

Warnings and precautions

Talk to your doctor or pharmacist before taking Nilemdo:

- if you ever had gout;
- if you have severe kidney problems;
- if you have severe liver problems.

Your doctor may do a blood test before you start taking Nilemdo. This is to check how well your liver is working.

If you are taking other medicine called statins (medicines used to lower cholesterol), talk promptly to your doctor about any unexplained muscle pain, tenderness, or weakness (see 'Other medicines and Nilemdo').

If you plan to become pregnant, talk to your doctor first. Your doctor will advise you how to stop taking Nilemdo before stopping any form of contraception.

Children and adolescents

Do not give Nilemdo to children and adolescents under 18 years of age. The use of Nilemdo has not been studied in this age group.

Other medicines and Nilemdo

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor if you are taking medicine(s) with any of the following active substances:

- atorvastatin, fluvastatin, pitavastatin, pravastatin, rosuvastatin, simvastatin (used to lower cholesterol and known as statins).
The risk of muscle disease may increase when taking both a statin and Nilemdo. Tell your doctor immediately about any unexplained muscle pain, tenderness or weakness.
- bosentan (used to manage a condition called pulmonary artery hypertension).
- fimasartan (used to treat high blood pressure and heart failure).
- asunaprevir, glecaprevir, grazoprevir, voxilaprevir (used to treat hepatitis C).

Pregnancy and breast-feeding

Do not take this medicine if you are pregnant, trying to get pregnant, or think you may be pregnant, as there is a possibility that it could harm an unborn baby. If you get pregnant while taking this medicine, call your doctor immediately and stop taking Nilemdo.

• Pregnancy

Before starting treatment, you should confirm you are not pregnant and are using effective contraception, as advised by your doctor. If you use contraceptive pills and suffer from an episode of diarrhoea or vomiting that lasts more than 2 days, you must use an alternative method of contraception (e.g. condoms, diaphragm) for 7 days following resolution of symptoms.

If, after you have started treatment with Nilemdo, you decide that you would like to become pregnant, tell your doctor, as your treatment will need to be changed.

• Breast-feeding

Do not take Nilemdo if you are breast-feeding because it is not known if Nilemdo passes into milk.

Driving and using machines

Nilemdo has no or little influence on the ability to drive and use machines.

Nilemdo contains lactose and sodium

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

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

3. HOW TO TAKE NILEMDO

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one tablet once daily.

Swallow the tablet whole with food or between meals.

If you take more Nilemdo than you should

Contact your doctor or pharmacist immediately.

If you forget to take Nilemdo

If you notice that you forgot:

- a dose late in a day, take the missed dose and take the next dose at your regular time the next day.
- the previous day's dose, take your tablet at the regular time and do not make up for the forgotten dose.

If you stop taking Nilemdo

Do not stop taking Nilemdo without your doctor's permission as your cholesterol may rise again.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Side effects can occur with the following frequencies:

Common (may affect up to 1 in 10 people)

- lower number of red blood cells (anaemia)
- increased levels of uric acid in blood, gout
- pain in shoulders, legs, or arms
- blood test results indicating liver abnormalities
- decreased glomerular filtration rate (a measure of how well your kidneys are working)

Uncommon (may affect up to 1 in 100 people)

- decreased haemoglobin (a protein in red blood cells that carries oxygen)
- raised creatinine and blood urea nitrogen (laboratory tests of kidney function)
- weight loss

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: 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 NILEMDO

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date, which is stated on the blister and carton. The expiry date refers to the last day of the month.
- This medicine does not require any special storage conditions.
- If the tablet becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.
- Do not throw away any medicine 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 Nilemdo contains

The active substance is bempedoic acid. Each film-coated tablet contains 180 mg of bempedoic acid.

The other ingredients are lactose monohydrate (see end of section 2 under 'Nilemdo contains lactose and sodium'), microcrystalline cellulose (E460), sodium starch glycolate (Type A grade) (see end of section 2 under 'Nilemdo contains lactose and sodium'), hydroxypropyl cellulose (E463), magnesium stearate (E470b), silica, colloidal anhydrous (E551), partially hydrolysed poly(vinyl alcohol) (E1203), talc (E553b), titanium dioxide (E171), macrogol/PEG (E1521).

What Nilemdo looks like and contents of the pack

Film-coated tablets are white to off-white, oval, debossed with "180" on one side and "ESP" on the other side. Tablet dimensions: 13.97 mm × 6.60 mm × 4.80 mm.

Pack size: 28 film-coated tablets.

Manufacturer

Daiichi Sankyo Europe GmbH, Luitpoldstrasse 1, 85276 Pfaffenhofen, Germany.

Procured from within the EU for the Product Licence Holder:

IMED Healthcare Ltd, Unit E, The Business Centre, 5-7 Tobermore Road, Draperstown, Magherafelt, BT45 7AG, UK.

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PL 33543/0320

Leaflet revision date: 27/01/2024

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For any information about this medicine, please contact the Product Licence Holder: IMED Healthcare Limited, Unit E, The Business Centre, 5-7 Tobermore Road, Draperstown, Magherafelt, BT45 7AG, United Kingdom. Tel: 028 7962 9988.

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