



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Nilemdo (*bempedoic acid*)

An overview of Nilemdo and why it is authorised in the EU

What is Nilemdo and what is it used for?

Nilemdo is a medicine for lowering levels of cholesterol in the blood. It contains the active substance bempedoic acid.

The medicine is used to reduce blood cholesterol levels in adults with primary hypercholesterolaemia or mixed dyslipidaemia (conditions that cause high levels of fats, including cholesterol, in the blood). Patients taking the medicine are required to be on a low-fat diet.

Nilemdo is also used to reduce the risk of heart problems in adults with, or at high risk for, problems affecting the heart and blood circulation, such as heart attack, stroke or other problems of the circulatory system caused by fatty deposits build up in the walls of the arteries (atherosclerosis).

Nilemdo is used in combination with a statin, with or without other fat-lowering medicines (mainly ezetimibe). Nilemdo can also be used alone or in combination with other fat-lowering medicines without a statin in patients who cannot take statins, or without a statin but with ezetimibe.

How is Nilemdo used?

Nilemdo can only be obtained with a prescription; the medicine is available as a tablet taken by mouth once a day.

For more information about using Nilemdo, see the package leaflet or contact your doctor or pharmacist.

How does Nilemdo work?

Nilemdo blocks an enzyme in the liver called adenosine triphosphate citrate lyase, which is involved in making cholesterol. By blocking this enzyme, Nilemdo reduces blood levels of cholesterol, including low-density lipoprotein (LDL) cholesterol (known as 'bad' cholesterol), and other fatty substances made by the liver.



What benefits of Nilemdo have been shown in studies?

Primary hypercholesterolaemia or mixed dyslipidaemia

Nilemdo effectively reduced LDL cholesterol levels in four main studies involving adults with hypercholesterolaemia or mixed dyslipidaemia, in which Nilemdo was compared with placebo (a dummy treatment).

Two of the studies involved a total of 3,009 patients who were also taking the maximum tolerated doses of statins with or without other fat-lowering medicines. After three months, patients taking Nilemdo had reductions in LDL cholesterol levels of 15% in one study and 17% in the other, while there was a rise in LDL cholesterol levels of around 2% in patients taking placebo in both studies.

The other two studies involved a total of 614 patients who were not able to take a statin or were only taking a low dose. After three months, LDL cholesterol levels in these studies were reduced by 23% and 24% in patients taking Nilemdo compared with a decrease of 1% and an increase of 5% respectively in patients taking placebo.

Atherosclerotic cardiovascular disease

Nilemdo was studied in almost 14,000 adults who were intolerant to statins and who had or were at high risk for cardiovascular disease. After at least 2 years of treatment, 11.7% (819 out of 6,992) of patients given Nilemdo experienced a cardiovascular event (meaning death, heart attack, stroke, or surgery to restore blood flow to the heart), compared with 13.3% (927 out of 6,978) of patients given placebo.

What are the risks associated with Nilemdo?

For the full list of side effects and restrictions with Nilemdo, see the package leaflet.

The most common side effects with Nilemdo (which may affect up to 1 in 10 people) are hyperuricaemia (high blood levels of uric acid), pain in arms or legs, anaemia (low levels of red blood cells) and gout (painful inflammation in the joints caused by high blood levels of uric acid).

Nilemdo must not be used in pregnant or breastfeeding women. When Nilemdo is taken in combination with a statin called simvastatin, it can increase the risk of side effects of simvastatin. Therefore, Nilemdo must not be used with doses of simvastatin higher than 40 mg daily.

Why is Nilemdo authorised in the EU?

Nilemdo was shown to reduce levels of LDL cholesterol in adults with hypercholesterolaemia or mixed dyslipidaemia and lower the risk of major cardiovascular events in adults who have or are at high risk for cardiovascular disease. The safety profile of Nilemdo was considered acceptable. Nilemdo may increase the risk of side effects of statins and these should be managed appropriately. The European Medicines Agency therefore decided that Nilemdo's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Nilemdo?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Nilemdo have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Nilemdo are continuously monitored. Side effects reported with Nilemdo are carefully evaluated and any necessary action taken to protect patients.

Other information about Nilemdo

Nilemdo received a marketing authorisation valid throughout the EU on 1 April 2020.

Further information on Nilemdo can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/nilemdo.

This overview was last updated in 04-2024.