EMA/65186/2020
EMEA/H/C/004958

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 is used in patients 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 used in combination with a statin, with or without other fat-lowering medicines, in patients whose cholesterol levels are not lowered enough by the maximum dose of a statin. Nilemdo can also be used alone or in combination with other fat-lowering medicines in patients who cannot take statins.

Nilemdo contains the active substance bempedoic acid.

How is Nilemdo used?

Nilemdo can only be obtained with a prescription and is available as 180-mg tablets. The recommended dose of Nilemdo is one tablet 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?

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).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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 both studies in patients taking placebo.

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.

What are the risks associated with Nilemdo?

The most common side effects with Nilemdo (which may affect more than 1 in 100 people) are hyperuricaemia (high blood levels of uric acid), pain in arms or legs, and anaemia (low red blood cell counts).

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

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

Why is Nilemdo authorised in the EU?

Nilemdo was shown to reduce levels of LDL cholesterol. Although there are no studies showing reduction in heart disease with the medicine, lowering LDL-cholesterol is expected to reduce the risk of heart 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 04-2020.