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Nustendi (*bempedoic acid / ezetimibe*)

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

What is Nustendi and what is it used for?

Nustendi 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.

Nustendi contains the active substances bempedoic acid and ezetimibe.

Nustendi is used in combination with a statin in patients whose cholesterol levels are not lowered enough by the maximum dose of a statin taken together with ezetimibe. Nustendi can also be used alone in patients who cannot take statins and whose cholesterol levels are not lowered enough by ezetimibe. The medicine can be used to replace separate tablets of bempedoic acid and ezetimibe in patients already taking them.

How is Nustendi used?

Nustendi can only be obtained with a prescription and is available as tablets (180 mg bempedoic acid / 10 mg ezetimibe). The recommended dose of Nustendi is one tablet a day.

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

How does Nustendi work?

The active substances in Nustendi, bempedoic acid and ezetimibe, work in different ways to lower blood cholesterol.

Bempedoic acid works by blocking an enzyme in the liver called adenosine triphosphate citrate lyase, which is involved in making cholesterol. This leads to a reduction of the level of low-density lipoprotein (LDL) cholesterol, known as 'bad' cholesterol, in the blood and also reduces other fatty substances made by the liver.

Ezetimibe works by binding to a gut protein called 'Niemann-Pick C1 Like 1', preventing cholesterol from being absorbed into the blood from the gut.

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What benefits of Nustendi have been shown in studies?

Two studies showed that bempedoic acid and ezetimibe (the active substances of Nustendi) effectively reduced LDL cholesterol levels in patients with hypercholesterolaemia and heart disease or who were at high risk of heart disease. High cholesterol is a risk factor for heart disease.

The first study involved 382 patients also taking the maximum tolerated doses of statins. After three months, LDL cholesterol levels were reduced by 36% in patients taking bempedoic acid and ezetimibe compared with a reduction of 23% with ezetimibe alone, 17% with bempedoic acid alone and an increase of around 2% with placebo (a dummy treatment).

The second study involved 269 patients with high cholesterol levels who were not able to take a statin or were taking a low dose of a statin. All the patients were also taking ezetimibe. After three months, LDL cholesterol levels were reduced by 23% in patients taking bempedoic acid in addition to ezetimibe compared with an increase of around 5% in patients taking placebo and ezetimibe.

What are the risks associated with Nustendi?

The most common side effects with Nustendi (which may affect around 1 in 20 people) are hyperuricaemia (high blood levels of uric acid) and constipation.

Nustendi must not be used in pregnant or breast-feeding women. When Nustendi 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. Nustendi must not be taken with a statin in patients with active liver disease or with unexplained high levels of serum transaminases (blood test results that could indicate liver problems).

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

Why is Nustendi authorised in the EU?

Nustendi was shown to reduce levels of LDL cholesterol and so is expected to help reduce the risk of heart disease. The safety profile of Nustendi was considered acceptable. Nustendi may increase the risk of side effects of statins and these should be managed appropriately. The European Medicines Agency therefore decided that Nustendi'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 Nustendi?

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

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

Other information about Nustendi

Nustendi received a marketing authorisation valid throughout the EU on 27 March 2020.

Further information on Nustendi can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/nustendi.

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