Package leaflet: Information for the patient

Nustendi 180 mg/10 mg film-coated tablet
bempedoic acid/ezetimibe

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 Nustendi is and what it is used for

What Nustendi is and how it works

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

Nustendi contains two active substances, which reduce your cholesterol in two ways:
- bempedoic acid decreases the production of cholesterol in the liver and increases the removal of LDL-cholesterol from the blood;
- ezetimibe works in your bowel by reducing the amount of cholesterol absorbed from food.

What Nustendi 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.

Nustendi is given:
- if you have been using a statin (such as simvastatin, a commonly used medicine that treats high cholesterol) together with ezetimibe and this does not lower your LDL-cholesterol sufficiently;
- if you have been using ezetimibe and this does not lower your LDL-cholesterol sufficiently;
- to replace bempedoic acid and ezetimibe if you have been using these medicines as separate tablets.

2. What you need to know before you take Nustendi

Do not take Nustendi:

- if you are allergic to bempedoic acid, ezetimibe 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);
- with a statin if you currently have liver problems.
- Nustendi contains ezetimibe. When Nustendi is given together with a statin, you should also read the information relating to ezetimibe in the Package leaflet of that specific statin.

Warnings and precautions

Talk to your doctor or pharmacist before taking Nustendi:
- if you ever had gout;
- if you have severe kidney problems;
- if you have moderate or severe liver problems. Nustendi is not recommended in this case.

Your doctor should do a blood test before you start taking Nustendi with a statin (medicine used to lower cholesterol). This is to check how well your liver is working.

If you are taking statins talk promptly to your doctor about any unexplained muscle pain, tenderness, or weakness (see 'Other medicines and Nustendi').

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

Children and adolescents

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

Other medicines and Nustendi

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 Nustendi. 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).
- fenofibrate or gemfibrozil (also used to lower cholesterol).
  No information is available on the effects of using Nustendi with cholesterol-lowering medicines called fibrates.
- ciclosporin (often used in organ transplant patients).
- cholestyramine (also used to lower cholesterol), because it affects the way ezetimibe works.
- medicines to prevent blood clots, such as warfarin as well as acenocoumarol, fluindione, and phenprocoumon.

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 Nustendi.

- **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 Nustendi, 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 Nustendi if you are breast-feeding because it is not known if Nustendi passes into milk.

Driving and using machines

Nustendi has minor influence on the ability to drive and use machines.

However, some people may get dizzy after taking Nustendi. Avoid driving or using machines if you think your ability to react is reduced.

Nustendi 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 Nustendi

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.

If you are taking colestyramine, take Nustendi either at least 2 hours before or at least 4 hours after taking colestyramine.

Swallow the tablet whole with food or between meals.

If you take more Nustendi than you should

Contact your doctor or pharmacist immediately.

If you forget to take Nustendi

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 Nustendi

Do not stop taking Nustendi 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.

Contact your doctor immediately if you have any of the following serious side effects (frequencies are unknown):
- muscle pain, tenderness or weakness (myopathy/rhabdomyolysis)
- yellowish skin and eyes, abdominal pain, dark urine, swollen ankles, decreased appetite, and feeling tired that could be signes of liver problems (hepatitis)
- allergic reactions including rash and hives; raised red rash, sometimes with target-shaped lesions (hypersensitivity/erythema multiforme)
- difficulties breathing, or swelling of the face, lips, throat or tongue (anaphylaxis/angioedema)
- gallstones or inflammation of the gallbladder (cholelithiasis/cholecystitis) which may cause abdominal pain, nausea, vomiting, inflammation of the pancreas often with severe abdominal pain (pancreatitis)
- reduction in blood platelets, which may cause bruising/bleeding (thrombocytopenia)

Other side effects can occur with the following frequencies:

Common (may affect up to 1 in 10 people)
- lower number of red blood cells (anaemia)
- decreased haemoglobin (a protein in red blood cells that carries oxygen)
- increased levels of uric acid in blood
- high levels of uric acid in your blood causing swollen, painful joints (gout)
- decreased appetite
- dizziness, headache
- high blood pressure
- cough
- constipation, diarrhoea, abdominal pain
- nausea
- dry mouth
- abdominal bloating and gas, inflammation of the stomach lining (gastritis)
- blood test results indicating liver abnormalities
- muscle spasm, muscle pain, pain in shoulders, legs or arms, back pain
- blood test showing raised creatine kinase (a laboratory test of muscle damage)
- muscle weakness, joint pain (arthralgia)
- raised creatinine and blood urean nitrogen (laboratory tests of kidney function)
- unusual tiredness (fatigue) or weakness (asthenia)
- decreased glomerular filtration rate (a measure of how well your kidneys are working)

Uncommon (may affect up to 1 in 100 people)
- hot flush
- pain in the upper part of stomach, heartburn, indigestion
- itching
- swelling of the legs or hands
- neck pain, chest pain, pain
- weight loss
- muscular weakness

Not known (frequency cannot be estimated from available data)
- tingling sensation
- depression
- shortness of breath

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 Nustendi

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 temperature storage conditions. Store in the original package in order to protect from moisture.

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 Nustendi contains

- The active substances are bempedoic acid and ezetimibe. Each film-coated tablet contains 180 mg of bempedoic acid and 10 mg of ezetimibe.
- The other ingredients are:
  - lactose monohydrate (see end of section 2 under ‘Nustendi contains lactose and sodium’)
  - microcrystalline cellulose (E460)
  - sodium starch glycolate (Type A grade) (see end of section 2 under ‘Nustendi contains lactose and sodium’)
  - hydroxypropyl cellulose (E463)
  - magnesium stearate (E470b)
  - silica, colloidal anhydrous (E551)

- sodium laurilsulfate (E487) (see end of section 2 under 'Nustendi contains lactose and sodium')
- povidone (K30) (E1201)
- partially hydrolysed poly(vinyl alcohol) (E1203), talc (E553b), titanium dioxide (E171), Indigo Carmine Aluminium Lake (E132), glycerol monocaprylocaprate, Brilliant Blue FCF Aluminium Lake (E133)

What Nustendi looks like and contents of the pack

Film-coated tablets are blue, oval, debossed with "818" on one side and "ESP" on the other side. Tablet dimensions: 15 mm × 7 mm × 5 mm.

The following pack sizes are registered: 10, 14, 28, 30, 84, 90, 98, or 100 film-coated tablets or unit dose blisters in cartons of 10 x 1, 50 x 1, or 100 x 1 film-coated tablets.

Not all pack sizes may be marketed.

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