

This digital patient guide, developed by Daiichi Sankyo UK, is intended for healthcare professionals to download and provide to their patients once the decision to prescribe the medicine has been taken.

Understanding your treatment with Nustendi[®] (bempedoic acid and ezetimibe)

This guide is intended for adult patients over the age of 18 who have been prescribed Nustendi[®].

You must read the Nustendi[®] Patient Information Leaflet provided with your medicine.

This guide does not replace the Patient Information Leaflet.

Only for distribution by healthcare professionals. For further advice consult your health professional.

Reporting of side effects: If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Patient Information Leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects, you can help provide more information on the safety of this medicine.

If you are currently taking a medicine called simvastatin at a dose greater than 40 mg daily you must not take Nustendi[®] and should contact your doctor, pharmacist or nurse for further advice.

Contents

- 2 What is this guide about?**
- 3 What is cholesterol?**
- 4 What can cause high levels of bad cholesterol?**
- 5 How does Nustendi[®] work to lower bad cholesterol?**
- 6 What do I need to know before taking Nustendi[®]?**
- 8 How do I take Nustendi[®]?**
- 9 Can I expect any side effects with Nustendi[®]?**
- 11 Pregnancy and breastfeeding information for women of child-bearing potential**
- 12 What should I do if I experience any side effects?**

What is this guide about?

You have been given this guide because your doctor has prescribed you Nustendi® to treat your high cholesterol.

Here, you will find information on your condition and how your medicine works to lower cholesterol in your blood. You can also find useful guidance on how to take your medicine and what to do if you experience any potential side effects.

The information in this guide does not replace the information in the Nustendi® Patient Information Leaflet provided with your medicine, which you must read prior to starting Nustendi®. You can also speak to your doctor, pharmacist or nurse to learn more.

What is cholesterol?

Cholesterol is a fatty substance produced by the liver and can also be found in some foods. We all need a certain amount of cholesterol in our blood to keep healthy but too much can clog up our arteries and lead to health problems such as heart attacks and strokes.

How does good and bad cholesterol affect arteries?

There are two main types of cholesterol:



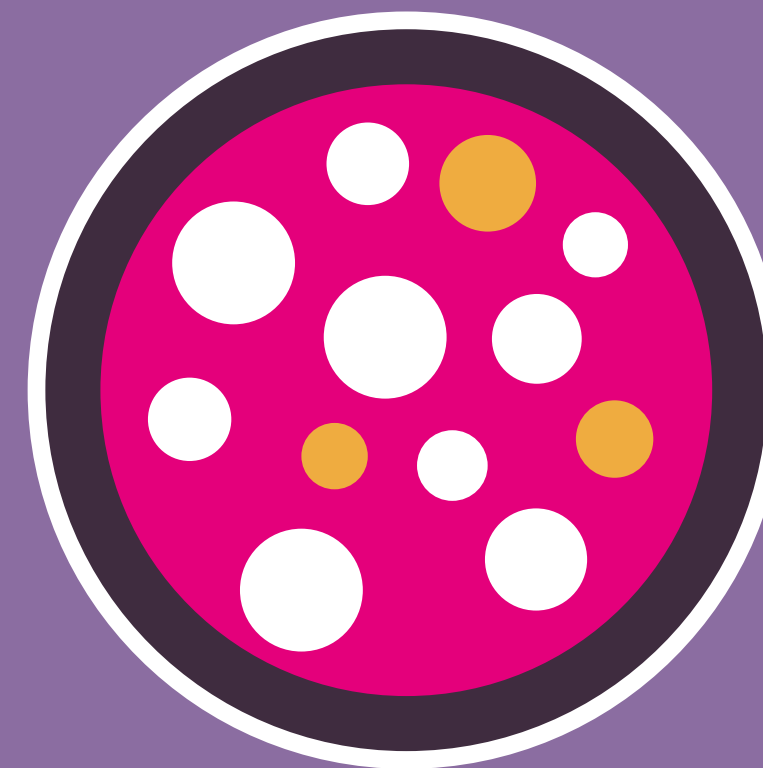
Good cholesterol (or HDL-C)

This is associated with lowering your risk of heart disease or having a stroke



Bad cholesterol (or LDL-C)

This can block your arteries, increasing your risk of having a heart attack or stroke



Healthy artery

High levels of good cholesterol,
low levels of bad cholesterol



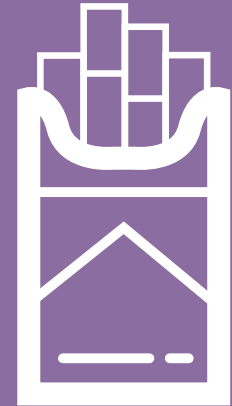
Artery narrowed

Too much bad cholesterol,
not enough good cholesterol

What can cause high levels of bad cholesterol?



Eating fatty foods



Smoking



Being overweight



Drinking alcohol



Not getting enough
regular exercise



Inherited through family

Managing cholesterol levels through healthy living

You may be able to modify your cholesterol levels by making lifestyle changes. These can include eating healthily, exercising regularly, reducing alcohol intake and quitting smoking. However, when lifestyle changes aren't doing enough, you may need treatment with cholesterol-lowering therapies, such as Nustendi®.

Why have I been prescribed Nustendi®?

You have been prescribed Nustendi® to help lower bad cholesterol (or LDL-C) in your blood. Your doctor may have already prescribed you a statin or other cholesterol-lowering medicines. **If you are taking Nustendi® with other medicines, it's important to take them all exactly as your doctor has prescribed. This will give you the best chance of lowering your bad cholesterol.**

How does Nustendi® work to lower bad cholesterol?

Nustendi® contains two active ingredients called **bempedoic acid** and **ezetimibe**, which lower bad cholesterol (or LDL-C) in different ways.

Bempedoic acid works in your liver

Bempedoic acid is activated in the liver. After activation, bempedoic acid decreases the production of cholesterol in the liver which increases the removal of bad cholesterol (or LDL-C) from the blood.



Ezetimibe works in your bowel

Ezetimibe works in your bowel by reducing the amount of cholesterol absorbed from food.



Nustendi® is a different type of medicine to a statin and works in a different way. If you want to know more about how Nustendi® works to lower your bad cholesterol (or LDL-C), talk to your doctor, pharmacist or nurse.

What do I need to know before taking Nustendi®?

Do not take Nustendi®:

- If you are pregnant, trying to get pregnant, or think you may be pregnant
- If you are allergic to bempedoic acid, ezetimibe or any ingredients listed in section 6 of the Patient Information Leaflet
- 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 Patient Information Leaflet of that specific statin.

Do not give Nustendi® to children and adolescents under 18 years of age.

Always talk to your doctor, pharmacist or nurse before stopping treatment.

What do I need to know before taking Nustendi®?

Before taking Nustendi®, you should speak to your doctor, pharmacist or nurse about:

- If you have ever had gout
- If you are pregnant, trying to get pregnant or think you may be pregnant
- If you have severe kidney problems
- If you have moderate or severe liver problems. Nustendi® is not recommended in this case

- Any other medicines that you are taking, have recently taken or might take.

Please refer to the Patient Information Leaflet for a list of medicines that you must inform your prescriber if you are taking

Prior to starting therapy:

Your doctor should do a blood test before you start taking Nustendi® with a statin (another 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.

If you take Nustendi® with another type of medicine called fibrates, your doctor should do a blood test at four weeks after starting Nustendi® and periodically afterwards to monitor:

- a type of fat (also called triglycerides) and
- 'good' cholesterol (also called "HDL-cholesterol")

How do I take Nustendi®?



Take one tablet once a day with or without food, whichever is more convenient



Swallow your tablet whole. It's important not to crush, split or chew the tablet



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

If you take more Nustendi® than you should, contact your doctor, pharmacist or nurse immediately. If you notice that you forgot a dose late in a day, take the missed dose as soon as you remember, and take the next dose at your regular time the next day. If you notice that you forgot the previous day's dose, take your tablet at the regular time and do not make up for the forgotten dose.

Nustendi® has minor influence on the ability to drive and use machines, and some people may get dizzy after taking Nustendi®. Avoid driving or using machines if you think your ability to react is reduced.

Take Nustendi® exactly as your doctor, pharmacist or nurse has recommended. Talk to your doctor, pharmacist or nurse if you have any questions or concerns.

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

Can I expect any side effects with Nustendi®?

Like all medicines, Nustendi® can cause side effects, although not everybody gets them.

A list of possible side effects can be found in the Patient Information Leaflet provided with your medicine, which you must read before starting treatment.

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 signs 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)

Can I expect any side effects with Nustendi®?

Common side effects (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 urea 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)

The risk of muscle disease may increase when taking both a statin and Nustendi®. Tell your doctor, pharmacist or nurse immediately about any unexplained muscle pain, tenderness or weakness.

This is not an exhaustive list of side effects. Please refer to the Patient Information Leaflet provided with your medicine for more information. If you experience any possible side effects including those not listed, talk to your doctor, pharmacist or nurse.

Pregnancy and breastfeeding information for women of child-bearing potential

You must read the Nustendi® Patient Information Leaflet provided with your medicine. This guide does not replace the Patient Information Leaflet.

Pregnancy

Do not take this medicine if you are pregnant, trying to get pregnant, or think you may be pregnant.

If you get pregnant while taking this medicine, call your doctor immediately and stop taking Nustendi®.

- 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

If you are breast-feeding, ask your doctor, pharmacist or nurse for advice before taking this medicine because Nustendi® may pass into your breast-milk.

What should I do if I experience any side effects?

Reporting of side effects: **If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Patient Information Leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.**

By reporting side effects, you can help provide more information on the safety of this medicine.