

Patient Information
NEXLETOL™ (NEX-le-tol)
(bempedoic acid)
tablets, for oral use

What is NEXLETOL?

NEXLETOL is a prescription medicine used along with diet and other lipid-lowering medicines in the treatment of adults with:

- heterozygous familial hypercholesterolemia (HeFH). HeFH is an inherited condition that causes high levels of “bad” cholesterol called low density lipoprotein (LDL).
- known heart disease who need additional lowering of “bad” cholesterol (LDL-C) levels.

It is not known if NEXLETOL can decrease problems from high cholesterol, such as heart attacks, stroke, death, or other heart problems.

It is not known if NEXLETOL is safe and effective in people with severe kidney problems including people with end-stage kidney disease who are on dialysis.

It is not known if NEXLETOL is safe and effective in people with severe liver problems.

It is not known if NEXLETOL is safe and effective in children under 18 years of age.

Before you start taking NEXLETOL, tell your healthcare provider about all your medical conditions, including if you:

- have or had gout.
- have or had tendon problems.
- are pregnant. Tell your healthcare provider right away if you become pregnant while taking NEXLETOL. You and your healthcare provider will decide if you should take NEXLETOL while you are pregnant.
- are breastfeeding or plan to breastfeed. It is not known if NEXLETOL passes into your breast milk. You and your healthcare provider should decide if you will take NEXLETOL or breastfeed. You should not do both.
- have severe kidney problems.
- have severe liver problems.

NEXLETOL may affect the way other medicines work, and other medicines may affect how NEXLETOL works. **Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.**

Especially tell your healthcare provider if you take or plan to take simvastatin or pravastatin (other cholesterol lowering medicines). Taking simvastatin or pravastatin with NEXLETOL may increase your risk of developing muscle pain or weakness (myopathy).

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take NEXLETOL?

- Take NEXLETOL exactly as your healthcare provider tells you to take it. Check with your healthcare provider or pharmacist if you are not sure.
- Take 1 NEXLETOL tablet by mouth each day.
- You may take NEXLETOL with or without food.
- If you take too much NEXLETOL, call your poison control center at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What are possible side effects of NEXLETOL?

NEXLETOL may cause serious side effects, including:

- **increased levels of uric acid in your blood (hyperuricemia).** This can happen within 4 weeks of you starting NEXLETOL and continue throughout your treatment. Your healthcare provider may monitor your blood uric acid levels while you are taking NEXLETOL. High levels of blood uric acid may lead to gout. Call your healthcare provider if you have the following symptoms of hyperuricemia and gout:

- severe foot pain especially in the toe joint
- warm joints
- swelling
- tender joints
- joint redness

Gout may happen more in people who have had gout before but also can happen in people who have never had it before.

- **tendon rupture or injury. Tendon problems can happen in people who take NEXLETOL.** Tendons are tough cords of tissue that connect muscles to bones. Symptoms of tendon problems may include pain, swelling, tears, and inflammation of tendons including the arm, shoulder, and back of the ankle (Achilles).
 - **Tendon rupture can happen while you are taking NEXLETOL.** Tendon ruptures can happen within weeks or months of starting NEXLETOL.
 - **The risk of getting tendon problems while you take NEXLETOL is higher if you:**
 - are over 60 years of age
 - are taking antibiotics (fluoroquinolones)
 - have had tendon problems
 - are taking steroids (corticosteroids)
 - have renal failure
 - **Stop taking NEXLETOL immediately and get medical help right away if you get any of the following signs or symptoms of a tendon rupture:**
 - hear or feel a snap or pop in a tendon area
 - bruising right after an injury in a tendon area
 - unable to move the affected area or put weight on the affected area

Stop taking NEXLETOL until tendon rupture has been ruled out by your healthcare provider. Avoid exercise and using the affected area. The most common areas of pain and swelling are the rotator cuff (the shoulder), the biceps tendon (upper arm), and Achilles tendon at the back of the ankle. This can happen with other tendons.
 - **Talk to your healthcare provider about the risk of tendon rupture with continued use of NEXLETOL.** You may need a different lipid-lowering medicine to treat your cholesterol levels.

The most common side effects of NEXLETOL include:

- symptoms of the common cold, flu, or flu-like symptoms
- back pain
- stomach pain
- increased liver enzymes
- muscle spasms
- pain in shoulder, legs, or arms
- anemia
- bronchitis

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of NEXLETOL.

For more information, ask your healthcare provider or pharmacist. **Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.**

How should I store NEXLETOL?

- Store NEXLETOL in the original package at room temperature between 68°F to 77°F (20°C to 25°C).
- **Do not** throw away the packet that helps to keep your medicine dry (desiccant).

Keep NEXLETOL and all medicines out of the reach of children.

General information about the safe and effective use of NEXLETOL.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. **Do not** use NEXLETOL for a condition for which it was not prescribed. **Do not** give NEXLETOL to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about NEXLETOL that is written for healthcare professionals.

What are the ingredients in NEXLETOL?

- **active ingredient:** bempedoic acid
- **inactive ingredients:** colloidal silicon dioxide, hydroxyl propyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and sodium starch glycolate
- **tablet coating:** partially hydrolyzed polyvinyl alcohol, polyethylene glycol, talc, and titanium dioxide

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This Patient Package Insert has been approved by the U.S. Food and Drug Administration

Revised: 02/2020