

PATIENT INFORMATION
NEXLETOL® (NEX-le-tol)
(bempedoic acid)
tablets, for oral use

What is NEXLETOL?

NEXLETOL is a prescription medicine used:

- to lower the risk of heart attack and heart procedures like stent placement or bypass surgery, in adults who are unable to take recommended statin treatment (a cholesterol-lowering medicine), or are not taking a statin, who:
 - have known heart disease, or
 - are at high risk for heart disease but without known heart disease.
- along with diet and other cholesterol-lowering medicines, or alone when use with other cholesterol-lowering medicines is not possible, to reduce low-density lipoprotein (LDL, or bad cholesterol) in adults with high blood cholesterol levels called primary hyperlipidemia, including a type of high blood cholesterol called heterozygous familial hypercholesterolemia (HeFH).

It is not known if NEXLETOL is safe and effective in children.

Do not take NEXLETOL if you are allergic to bempedoic acid or any of the ingredients in NEXLETOL. See the end of this leaflet for a complete list of ingredients in NEXLETOL. Stop taking NEXLETOL and call your healthcare provider or go to the nearest hospital emergency room right away if you have any signs or symptoms of an allergic reaction including:

- swelling of your face, lips, mouth or tongue
- wheezing
- severe itching
- fast heart beat or pounding in your chest
- trouble breathing
- skin rashes, redness, or swelling
- dizziness or fainting

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 or think you may be 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. If you are pregnant during NEXLETOL treatment, you are encouraged to call Esperion at 1-833-377-7633 to share information about the health of you and your baby.
- 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.
- Your healthcare provider may do blood tests to check your LDL-C levels between 8 to 12 weeks after starting treatment with NEXLETOL.
- In case of overdose, get medical help or contact a live Poison Center expert right away at 1-800-222-1222. Advice is also available online at poisonhelp.org.

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
- **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, most commonly with the rotator cuff (the shoulder), the biceps tendon (upper arm), and Achilles tendon at the back of the ankle. This can also happen with other tendons. 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

The most common side effects of NEXLETOL in people with primary hyperlipidemia include:

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

The most common side effects of NEXLETOL in people with heart problems include:

- kidney problems
- anemia
- increased liver enzymes
- muscle spasms
- gallstones

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 doctor 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).

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

Manufactured for:
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This Patient Information has been approved by the U.S. Food and Drug Administration

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