PATIENT INFORMATION
NEXLIZET® (NEX-lee-zet)
(bempedoic acid and ezetimibe)
tablets, for oral use

What is NEXLIZET?

NEXLIZET is a prescription medicine that contains 2 cholesterol-lowering medicines, bempedoic acid and ezetimibe.

- NEXLIZET is used along with diet, with or without other cholesterol-lowering medicines, to reduce low-density lipoprotein (LDL, or bad cholesterol) in adults with high blood cholesterol levels called primary hyperlipidemia, including a type of high cholesterol called heterozygous familial hypercholesterolemia (HeFH).
- Bempedoic acid when used as a component of NEXLIZET is 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.

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

Do not take NEXLIZET if you are allergic to ezetimibe, bempedoic acid, or any of the ingredients in NEXLIZET. See the end of this leaflet for a complete list of ingredients in NEXLIZET. Stop taking NEXLIZET, 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 NEXLIZET, 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 NEXLIZET. You and your healthcare provider will decide if you should take NEXLIZET while you are pregnant. If you are pregnant during NEXLIZET 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 NEXLIZET passes into your breast milk. You and your healthcare provider should decide if you will take NEXLIZET or breastfeed. You should not do both.
- have severe kidney problems.
- have moderate or severe liver problems.

NEXLIZET may affect the way other medicines work, and other medicines may affect how NEXLIZET 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 NEXLIZET may increase your risk of developing muscle pain or weakness (myopathy).
- cyclosporine (often used in organ transplant patients)
- fibrates (used to lower cholesterol)
- cholestyramine (used to lower cholesterol)

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 NEXLIZET?

- Take NEXLIZET exactly as your healthcare provider tells you to take it. Check with your healthcare provider or pharmacist if you are not sure.
- Take 1 NEXLIZET tablet by mouth each day.
- Swallow the NEXLIZET tablet whole. **Do not** cut, chew, or crush the tablet.
- You may take NEXLIZET with or without food.
- If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule. Do not take 2 doses of NEXLIZET at the same time.
- If you take a medicine that lowers cholesterol by binding bile acids, such as colesevelam or cholestyramine, take NEXLIZET at least 2 hours before or 4 hours after you take bile acid binding medicines. Ask your healthcare provider if you are not sure if you take these medicines.
- Your healthcare provider may do blood tests to check your LDL-C levels between 8 to 12 weeks after starting treatment with NEXLIZET.
- In case of an 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 NEXLIZET?

NEXLIZET may cause serious side effects, including:

- **increased levels of uric acid in your blood (hyperuricemia).** This can happen within 4 weeks of you starting NEXLIZET and continue throughout your treatment. Your healthcare provider may monitor your blood uric acid levels while you are taking NEXLIZET. 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 bempedoic acid, one of the medicines in NEXLIZET.** 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 NEXLIZET.
  - **The risk of getting tendon problems while you take NEXLIZET 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 NEXLIZET 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

    Avoid exercise and using the affected area.

The most common side effects of NEXLIZET 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
- diarrhea
- joint pain
- swelling of sinuses (sinusitis)
- fatigue

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

- kidney problems
- muscle spasms

- anemia
- increased liver enzymes
- 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 NEXLIZET. Ask your healthcare provider or pharmacist for more information.

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 NEXLIZET?

- Store NEXLIZET in the original package at room temperature between 68ºF to 77ºF (20ºC to 25ºC).
- Protect from heat and moisture.
- **Do not** throw away the packet that helps to keep your medicine dry (desiccant).
- NEXLIZET comes in a bottle with a child-resistant cap.

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

General information about the safe and effective use of NEXLIZET.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. **Do not** use NEXLIZET for a condition for which it was not prescribed. **Do not** give NEXLIZET 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 NEXLIZET that is written for healthcare professionals.

What are the ingredients in NEXLIZET?

- **active ingredients:** bempedoic acid and ezetimibe
- **inactive ingredients:** colloidal silicon dioxide, hydroxy propyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone K30, sodium lauryl sulfate, sodium starch glycolate
- **tablet coating:** FD&C Blue #1/Brilliant Blue FCF Aluminum Lake, FD&C Blue #2/Indigo Carmine Aluminum Lake, glyceryl monocaprylocaprate, partially hydrolyzed polyvinyl alcohol, sodium lauryl sulfate, talc, and titanium dioxide

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