

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrLEQVIO™

Inclisiran Injection

Read this carefully before you start receiving **LEQVIO** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **LEQVIO**.

What is LEQVIO used for?

LEQVIO is used in adults to further lower your LDL (“bad” cholesterol) levels. It is for patients who are currently taking a statin (a medicine used to treat high cholesterol), sometimes in combination with another cholesterol-lowering medicine.

LEQVIO is used in addition to lifestyle changes, including diet in patients who have:

- Heterozygous familial hypercholesterolemia (HeFH) (an inherited genetic disorder that causes extremely high cholesterol levels), or
- Non-familial hypercholesterolemia (a condition that affects the way your body processes cholesterol) with atherosclerotic cardiovascular disease (a hardening of the arteries)

The effect of LEQVIO on heart problems such as heart attacks, stroke, or death is not known.

How does LEQVIO work?

LEQVIO contains inclisiran. Inclisiran lowers levels of “bad” cholesterol by interfering with RNA (a molecule present in your body’s cells) to break down a protein called PCSK9. This protein can increase “bad” cholesterol levels. By limiting the amount of PCSK9, LEQVIO can lower your levels of “bad” cholesterol.

What are the ingredients in LEQVIO?

Medicinal ingredients: inclisiran

Non-medicinal ingredients: phosphoric acid and sodium hydroxide (to adjust pH), and water for injection.

LEQVIO comes in the following dosage forms:

Solution: 284 mg / 1.5 mL (inclisiran as sodium)

Do not use LEQVIO if:

- you are allergic to inclisiran or any other ingredients in LEQVIO (listed above)

You will be receiving LEQVIO along with a statin, sometimes in combination with another cholesterol-lowering medicine. Please read the Patient Medication Information of those particular medicines.

To find this information:

- go online: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>

- contact your healthcare professional

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LEQVIO. Talk about any health conditions or problems you may have, including if you:

- are at a high risk of diabetes
- have liver problems
- have kidney problems

Other warnings you should know about:

Pregnancy: If you are pregnant, think you may be pregnant or planning to become pregnant talk to your doctor. LEQVIO should not be used if you are pregnant.

Breastfeeding: It is not known whether LEQVIO passes into breast milk. It is important to tell your doctor if you are breastfeeding or plan to do so. Your doctor will then help you decide whether to stop breastfeeding, or whether to stop LEQVIO, considering the benefit of breastfeeding to the baby and the benefit of LEQVIO to the mother.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

It is unlikely LEQVIO interacts with statins. LEQVIO is not expected to interact with other medicines even though it has not been tested.

How LEQVIO is given:

Before starting LEQVIO, you should be on a cholesterol-lowering diet and taking a statin, sometimes in combination with another cholesterol-lowering medicine. You should stay on the cholesterol-lowering diet and keep taking the statin (and cholesterol-lowering medicine) while you receive LEQVIO.

LEQVIO is given:

- by your healthcare professional
- as an injection under the skin (subcutaneous injection) in your stomach (abdomen)

Usual dose:

After you receive your first injection, you will be given your next dose at 3 months and then every 6 months.

Overdose:

If you think you, or a person you are caring for, has received too much LEQVIO, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss the appointment for your next dose, contact your healthcare professional as soon as you remember. Depending on how long it has been since your last injection, your dosing schedule may

change.

What are possible side effects from using LEQVIO?

These are not all the possible side effects you may have when taking LEQVIO. If you experience any side effects not listed here, tell your healthcare professional.

- Pain, redness or rash at the site of the injection
- Common cold, such as runny nose, sore throat or sinus infections (nasopharyngitis or upper respiratory tract infections)
- Pneumonia
- Diarrhea
- Cough
- Shortness of breath (dyspnea)
- Feeling dizzy
- Nausea
- Headache
- Back pain
- Joint pain (arthralgia)
- Pain in the hands and feet
- Urinary tract infection
- Lung infection (bronchitis)
- High blood sugar levels (diabetes)
- Stiff joints
- Muscle spasms
- Trouble sleeping
- Asthma

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Keep this medicine out of the sight and reach of children.

- Store between 15°C to 25°C. Do not freeze.

If you want more information about LEQVIO:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.novartis.ca), or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

Last Revised July 23, 2021