

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using Leqvio?

Leqvio contains the active ingredient inclisiran. Leqvio is used to lower LDL-cholesterol ('bad' cholesterol) in addition to a cholesterol-lowering diet and exercise if you are an adult with a high cholesterol level in your blood.

For more information, see Section [1. Why am I using Leqvio](#) in the full CMI.

2. What should I know before I use Leqvio?

Do not use if you have ever had an allergic reaction to Leqvio or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Leqvio?](#) in the full CMI.

3. What if I am taking other medicines?

Leqvio is not expected to interact with other medicines even though it has not been tested.

For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is Leqvio given?

- Leqvio is given as an injection under the skin in your abdomen, alternatively the upper arm or thigh. It will be given to you by a doctor or healthcare provider.
- The recommended dose is one injection initially, again at 3 months, followed by every 6 months.

More instructions can be found in Section [4. How is Leqvio given?](#) in the full CMI.

5. What should I know while using Leqvio?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Leqvio.
Things you should not do	• Do not use this medicine if you are allergic to inclisiran, or any of the ingredients listed at the end of this leaflet.
Driving or using machines	• Leqvio is not expected to affect your ability to drive or use machines.
Drinking alcohol	• There are no known interactions between Leqvio and alcohol

For more information, see Section [5. What should I know while using Leqvio?](#) in the full CMI.

6. Are there any side effects?

As with all medicines, patients treated with Leqvio may experience side effects, although not everybody gets them. If you notice any of the following side effects or if these side effects become severe, please tell your doctor or healthcare provider.

Common side effects include injection site reactions, such as pain, redness or rash. More serious side effects may include signs of allergic reaction (anaphylaxis) including trouble breathing or swallowing, swelling of the face, lips, tongue or throat, raised or itchy red bumps or feeling faint.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Leqvio®

Active ingredient(s): inclisiran

Consumer Medicine Information (CMI)

This leaflet provides important information about using Leqvio. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Leqvio.**

Where to find information in this leaflet:

1. [Why am I using Leqvio?](#)
2. [What should I know before I use Leqvio?](#)
3. [What if I am taking other medicines?](#)
4. [How is Leqvio given?](#)
5. [What should I know while using Leqvio?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using Leqvio?

Leqvio contains the active ingredient inclisiran. Leqvio is a cholesterol-lowering double stranded small interfering ribonucleic acid (siRNA).

Leqvio is used to lower levels of LDL-cholesterol ('bad' cholesterol), which can cause heart disease and blood circulation problems. LDL-cholesterol can build up in the walls of your arteries leading to narrowing of the arteries. This narrowing can slow or block blood flow to vital organs such as the heart and brain leading to a heart attack or stroke and other health problems.

You need to use Leqvio while also following a cholesterol-lowering diet and exercising.

Leqvio is used in adults with high LDL-cholesterol levels, in adults who have heart disease (such as a previous heart attack or stroke), or in adults with a higher chance of having a heart attack.

Leqvio may be used with other cholesterol-lowering medicines, for example a statin (a commonly used medicine that treats high cholesterol). Leqvio may also be used alone if your doctor say you cannot take a statin.

Inclisiran lowers levels of 'bad' cholesterol by silencing or turning off the gene for a protein called PCSK9.

2. What should I know before I use Leqvio?

Warnings

Do not use Leqvio if:

- you are allergic to inclisiran, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- take any medicines for any other conditions

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

The effects of Leqvio in pregnant women are not known. Check with your doctor if you are pregnant, intend to become pregnant, or think you may be pregnant when taking Leqvio.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known if Leqvio is found in breast milk. Your doctor can discuss the risks and benefits with you.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Leqvio is not expected to interact with other medicines even though it has not been tested.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Leqvio.

4. How is Leqvio given?

How much is given

- The recommended dose of Leqvio is one injection initially. Then you will be given your next dose at 3 months, and then every 6 months.
- Follow the instructions provided and use Leqvio until your doctor tells you to stop.

How Leqvio is given

- Leqvio is given as an injection under the skin (subcutaneous injection) in your abdomen. Alternatively, the upper arm or thigh.
- It will be given to you by a doctor or healthcare provider.

Before starting Leqvio you should be on a cholesterol-lowering diet and exercise as part of a lifestyle change, and it is likely that you will be taking a statin (a commonly used medicine that treats high cholesterol). You should stay on this cholesterol-lowering diet and exercise, and any medications as advised by your doctor while receiving

Leqvio, as they act together to provide maximum cholesterol control for you.

If you have missed a dose of Leqvio

If you miss your appointment to have Leqvio administered, contact your doctor or healthcare provider as soon as you remember so that you can arrange your next treatment.

If you have any further questions on the use of this medicine, ask your doctor or healthcare provider.

If you have been given too much Leqvio

It is unlikely you would be given too much Leqvio given that it is administered by a healthcare professional but if you think that you have been given too much, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Leqvio?

Things you should do

Remind any doctor, dentist or pharmacist that you are using Leqvio.

Tell your doctor or healthcare provider if you experience an allergic reaction, feel unwell, or have any side effects that worry you during or after injection.

Driving or using machines

Leqvio is not expected to affect your ability to drive or use machines.

How Leqvio is stored

Store below 30°C. Do not freeze.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Injection site reactions, such as pain, redness or rash	Speak to your doctor if you have any of these less serious side effects and

Less serious side effects	What to do
	they worry you.

Serious side effects

Serious side effects	What to do
Signs of allergic reaction (anaphylaxis): • Swelling of the face, lips, tongue or throat • Difficulty breathing or swallowing • Dizziness, feeling faint (may be sign of decreased blood pressure) • Severe itching of the skin, with a red rash or raised bumps	Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Leqvio contains

Active ingredient (main ingredient)	inclisiran
Other ingredients (inactive ingredients)	sodium hydroxide, phosphoric acid and water for injection

Do not take this medicine if you are allergic to any of these ingredients.

What Leqvio looks like

Leqvio is a pre-filled syringe containing a clear, colorless to pale yellow solution for injection essentially free of particulate (Aust R 342250).

Who distributes Leqvio

LEQVIO is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited
ABN 18 004 244 160
Level 25, Victoria Cross Tower
155 Miller Street
North Sydney NSW 2060
Telephone: 1 800 671 203
Website: www.novartis.com.au

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