

4. Side effects

Like with all medicines, using Leqvio may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Common side effects affect 1-10 in 100 users:

- Injection site reactions, such as pain, redness or rash.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Store below 30°C. Do not freeze.

The doctor, pharmacist or nurse will check this medicine and will discard it if it contains particles.

Do not throw away medicines via wastewater or household waste. Your doctor, pharmacist or nurse will throw away medicines that you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains: water for injections, sodium hydroxide, concentrated phosphoric acid. (See the section 'Leqvio contains sodium').

What the medicine looks like and contents of the pack

Leqvio is a clear, colourless to pale yellow solution, free of particulates.

Each pack contains one single-use pre-filled syringe with needle guard.

Registration holder and importer's name and address:

Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

Revised in October 2022 according to MOH guidelines

Registration number of the medicine in the Ministry of Health's National Drug Registry: 167-93-36715-99

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Leqvio 284 mg

Solution for injection in pre-filled syringe with needle guard for subcutaneous injection

Active ingredient:

Each pre-filled syringe with needle guard contains inclisiran sodium equivalent to 284 mg inclisiran in 1.5 ml solution.

Each ml contains inclisiran sodium equivalent to 189 mg inclisiran.

Inactive ingredients and allergens: See section 6 'Additional information' and section 2 under 'Important information about some of this medicine's ingredients'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

Leqvio is indicated for adults with primary hypercholesterolaemia (heterozygous familial and non familial) or mixed dyslipidaemia, as an adjunct to diet:

- in combination with a statin or statin with other lipid lowering therapies in patients unable to reach LDL cholesterol goals with the maximum tolerated dose of a statin, or
- alone or in combination with other lipid lowering therapies in patients who are statin intolerant, or for whom a statin is contraindicated.

Therapeutic group: fats (lipids) modifying agents, Other fats (lipids) modifying agents.

Leqvio contains the active substance inclisiran. Inclisiran lowers levels of LDL cholesterol ("bad" cholesterol), which can cause heart and blood circulation problems when levels are elevated.

Inclisiran works by interfering with RNA (genetic material in body cells) to limit the production of a protein called PCSK9. This protein can increase LDL cholesterol levels and preventing its production helps to lower your LDL cholesterol levels.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to inclisiran or to any of the other ingredients in this medicine (listed in section 6).

Special warnings about using this medicine

Before treatment with Leqvio, tell your doctor, pharmacist or nurse if:

- you are being treated with dialysis
- you have severe liver disease
- you have severe kidney disease

Children and adolescents:

This medicine is not intended for children and adolescents under the age of 18.

There is no information about the safety of use and effectiveness of this medicine in children and adolescents under the age of 18.

Drug interactions:

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Pregnancy, breast-feeding and fertility:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, consult your doctor, pharmacist or nurse before taking this medicine. There is limited information about use during pregnancy and therefore use of Leqvio should be avoided during pregnancy.

It is not yet known whether Leqvio passes into breast milk. Your doctor will help you to decide whether to continue breast-feeding or to start treatment with Leqvio. Your doctor will consider the benefits of treatment for you, compared with the potential risk of breast-feeding while taking the treatment for your baby.

Fertility

No information on the effect of Leqvio on human fertility is available.

Animal studies did not show any effects on fertility.

Driving and using machines:

Leqvio has a negligible effect or no effect at all on your ability to drive or use machines.

Important information about some of this medicine's ingredients:

Leqvio contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium free'.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions.

Check with your doctor, nurse or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.

The recommended dosage of Leqvio is usually 284 mg given by injection under the skin. The next dose is given after 3 months, followed by further doses every 6 months.

Do not exceed the recommended dose.

Before starting treatment with Leqvio, you should strictly follow to a diet to lower your cholesterol and it is likely that you will be taking a statin. You should stay on this diet and keep taking the statin all the time you are taking Leqvio.

Leqvio is intended for injection under the skin in the area of the abdomen. Alternative injection sites include the upper arm or thigh. Leqvio will be given to you by a doctor or nurse (healthcare professional).

If you have accidentally taken a higher dose

This medicine will be given to you by a doctor or nurse (healthcare professional). In the highly unlikely event that you are given too much medicine (an overdose), the doctor or other healthcare professional will check you for side effects.

If you forget to take Leqvio

If you miss the date for your injection, contact your doctor or nurse as soon as you can to schedule your next injection.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.