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 for subcutaneous injection

Active ingredient:
Each pre-filled syringe 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 intended 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 blood lipid lowering therapies in patients unable to reach LDL cholesterol goals with the maximum tolerated dose of a statin, or
- monotherapy or in combination with other blood lipid lowering therapies in patients who are statin intolerant, or for whom a statin is contraindicated.

Therapeutic group: lipid modifying agents, other lipid 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.

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.

Storage conditions: 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.
Also 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.

Registration holder and importer's name and address:
Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

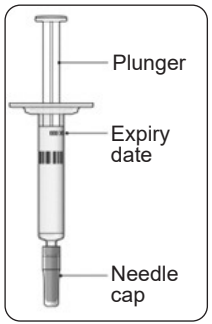
Revised in June 2024.

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

המידע הבא מיועד לאנשי הצוות הרפואי בלבד:
The following information is intended for healthcare professionals only:
المعلومات التالية معدّة للطاقم الطبيّ فقط:

הוראות שימוש בלקוויו מזרק מוכן לשימוש ללא מגן מחט:
Instructions for Use for Leqvio pre-filled syringe without needle guard:
تعليمات استعمال ليكفيو محقنة جاهزة للاستعمال بدون واقي إبرة:

This section contains information on how to inject Leqvio.



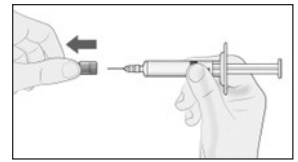
Important information you need to know before injecting Leqvio

- **Do not** use the pre-filled syringe if any of the seals on the outer carton or the seal of the plastic tray are broken.
- **Do not** remove the needle cap until you are ready to inject.
- **Do not** use if the pre-filled syringe has been dropped after removing the needle cap.
- **Do not** try to re-use or take apart the pre-filled syringe.

Step 1. Inspect the pre-filled syringe
You may see air bubbles in the liquid, which is normal. **Do not** try to remove the air.

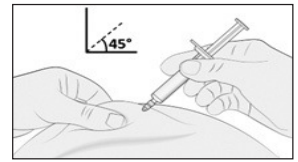
- **Do not** use the pre-filled syringe if it looks damaged or if any of the solution for injection has leaked out of the pre-filled syringe.

Step 2. Remove needle cap
Firmly pull straight to remove the needle cap from the pre-filled syringe. You may see a drop of liquid at the end of the needle. This is normal. **Do not** put the needle cap back on. Throw it away.

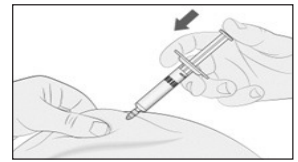


Note: **Do not** remove the needle cap until you are ready to inject. Early removal of the needle cap prior to injection can lead to drying of the drug product within the needle, which can result in needle clogging.

Step 3. Insert needle
Gently pinch the skin at the injection site and hold the pinch throughout the injection. With the other hand insert the needle into the skin at an angle of approximately 45 degrees as shown.



Step 4. Inject
Continue to pinch the skin. Slowly press the plunger **as far as it will go**. This will make sure that a full dose is injected.



Note: If you cannot depress the plunger following insertion of the needle, use a new pre-filled syringe.

Step 5. Complete injection and dispose of the pre-filled syringe
Remove the pre-filled syringe from the injection site. Do not put the needle cap back on.
Dispose of the pre-filled syringe in accordance with local requirements.