Package leaflet: Information for the patient

Leqvio® 284 mg solution for injection in pre-filled syringe
Pre-filled syringe with needle guard
inclisiran

▼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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Leqvio is and what it is used for

What Leqvio is and how it works
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 raised.

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.

What Leqvio is used for
Leqvio is used in addition to your cholesterol-lowering diet if you are an adult with a high cholesterol level in your blood (primary hypercholesterolaemia, including heterozygous familial and non-familial, or mixed dyslipidaemia).

Leqvio is given:
- together with a statin (a type of medicine that treats high cholesterol), sometimes combined with another cholesterol-lowering treatment if the maximum dose of the statin does not work well enough, or
- alone or together with other cholesterol-lowering medicines when statins do not work well or cannot be used.

2. What you need to know before you are given Leqvio

You must not be given Leqvio
- if you are allergic to inclisiran or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given Leqvio:
- if you are receiving dialysis
- if you have severe liver disease
- if you have severe kidney disease

Children and adolescents
Do not give this medicine to children and adolescents under 18 years of age, because there is no experience of using the medicine in this age group.

Other medicines and Leqvio
Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before you are given this medicine.

The use of Leqvio should be avoided during pregnancy.

It is not yet known whether Leqvio passes into human 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 potential benefits of treatment for you, compared with the health benefits and risks of breast-feeding for your baby.

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

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

3. How Leqvio is given

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

Before starting Leqvio you should be on a diet to lower your cholesterol and it is likely that you will be taking a statin. You should stay on this cholesterol-lowering diet and keep taking the statin all the time you receive Leqvio.

Leqvio is for injection under the skin of the abdomen; alternative injection sites include the upper arm or thigh. Leqvio will be given to you by a doctor, pharmacist or nurse (healthcare professional).

If you receive more Leqvio than you should
This medicine will be given to you by your doctor, pharmacist or nurse (healthcare professional). In the highly unlikely event that you are given too much (an overdose) the doctor or other healthcare professional will check you for side effects.

If you miss your dose of Leqvio
If you miss your appointment for your Leqvio injection, contact your doctor, pharmacist or nurse as soon as you can to arrange your next injection.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common (may affect up to 1 in 10 people)
- Injection site reactions, such as pain, redness or rash.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Leqvio

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

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions. Do not freeze.

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

Medicines should not be disposed of via wastewater or household waste. Your doctor, pharmacist or nurse will throw away medicines no longer being used. These measures will help protect the environment.

6. Contents of the pack and other information

What Leqvio contains
- The active substance is inclisiran. 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.
- The other ingredients are water for injections, sodium hydroxide (see section 2 “Leqvio contains sodium”) and concentrated phosphoric acid.

What Leqvio looks like and contents of the pack
Leqvio is a clear, colourless to pale yellow solution, essentially free of particulates.

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

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Novartis Pharmaceuticals UK Limited
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United Kingdom

Manufacturer
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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The following information is intended for healthcare professionals only:

Leqvio® 284 mg solution for injection in pre-filled syringe
Pre-filled syringe with needle guard
inclisiran

Healthcare professionals should refer to the Summary of Product Characteristics for full prescribing information.

Indication *(see section 4.1 of the SmPC)*

Leqvio is indicated in 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-C 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.

Posology (*see section 4.2 of the SmPC*)

The recommended dose is 284 mg inclisiran administered as a single subcutaneous injection: initially, again at 3 months, followed by every 6 months.

Missed doses
If a planned dose is missed by less than 3 months, inclisiran should be administered and dosing continued according to the patient's original schedule.

If a planned dose is missed by more than 3 months, a new dosing schedule should be started – inclisiran should be administered initially, again at 3 months, followed by every 6 months.

Treatment transition from monoclonal antibody PCSK9 inhibitors
Inclisiran can be administered immediately after the last dose of a monoclonal antibody PCSK9 inhibitor. To maintain LDL-C lowering it is recommended that inclisiran is administered within 2 weeks after the last dose of a monoclonal antibody PCSK9 inhibitor.

Special populations
Elderly (age ≥65 years)
No dose adjustment is necessary in elderly patients.

Hepatic impairment
No dose adjustments are necessary for patients with mild (Child-Pugh class A) or moderate (Child-Pugh class B) hepatic impairment. No data are available in patients with severe hepatic impairment (Child-Pugh class C). Inclisiran should be used with caution in patients with severe hepatic impairment.

Renal impairment
No dose adjustments are necessary for patients with mild, moderate or severe renal impairment or patients with end stage renal disease. There is limited experience wth inclisiran in patients with severe renal impairment. Inclisiran should be used with caution in these patients. See section 4.4 of the SmPC for precautions to take in case of haemodialysis.

Paediatric population
The safety and efficacy of inclisiran in children aged less than 18 years has not yet been established. No data are available.

Method of administration (*see section 4.2 of the SmPC*)

Subcutaneous use.

Inclisiran is for subcutaneous injection into the abdomen; alternative injection sites include the upper arm or thigh. Injections should not be given into areas of active skin disease or injury such as sunburns, skin rashes, inflammation, or skin infections.

Each 284 mg dose is administered using a single pre-filled syringe. Each pre-filled syringe is for single use only.

Inclisiran is intended for administration by a healthcare professional.

Contraindications (*see section 4.3 of the SmPC*)

Hypersensitivity to the active substance or to any of the excipients.

Special warnings and precautions (*see section 4.4 of the SmPC*)

Haemodialysis

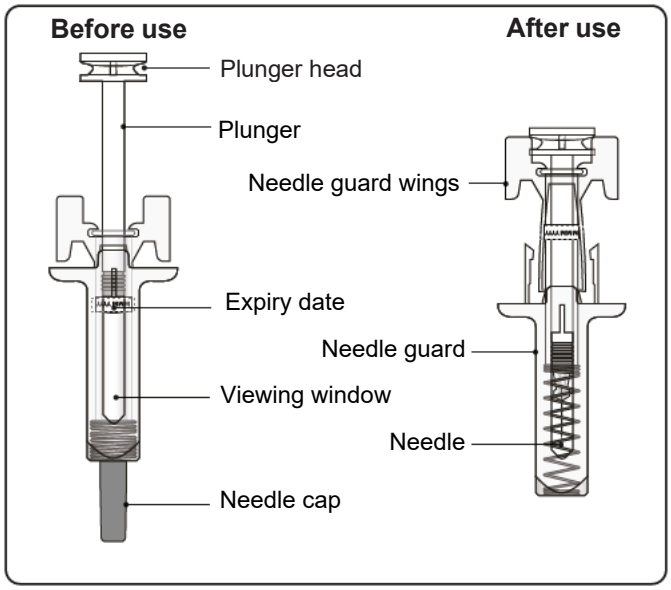
The effect of haemodialysis on inclisiran pharmacokinetics has not been studied. Considering that inclisiran is eliminated renally, haemodialysis should not be performed for at least 72 hours after inclisiran dosing.

Storage *(see section 6.4 of the SmPC)*

This medicinal product does not require any special storage conditions. Do not freeze.

Instructions for Use for Leqvio pre-filled syringe with needle guard

This section contains information on how to inject Leqvio.



Important information you need to know before injecting Leqvio

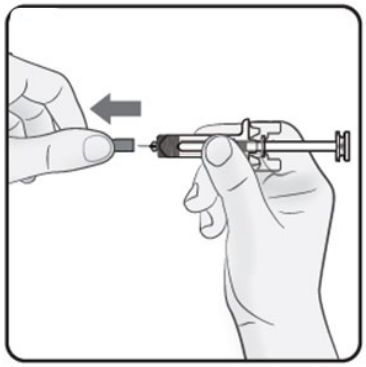
- **Do not** use the pre-filled syringe if any of the seals on the outer carton or the seal of the plastic tray are broken.
- **Do not** remove the needle cap until you are ready to inject.

- **Do not** use if the pre-filled syringe has been dropped onto a hard surface or dropped after removing the needle cap.
- **Do not** try to re-use or take apart the pre-filled syringe.
- The pre-filled syringe has a needle guard that will be activated to cover the needle after the injection is finished. The needle guard will help to prevent needle stick injuries to anyone who handles the pre-filled syringe after injection.

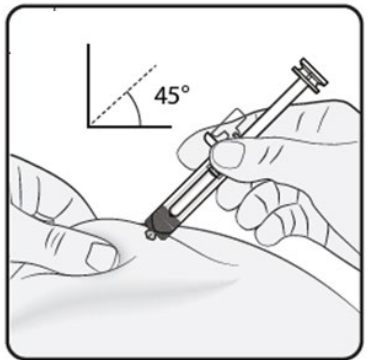
Step 1. Inspect the pre-filled syringe
You may see air bubbles in the liquid, which is normal. **Do not** try to remove the air.
- **Do not** use the pre-filled syringe if it looks damaged or if any of the solution for injection has leaked out of the pre-filled syringe.

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.

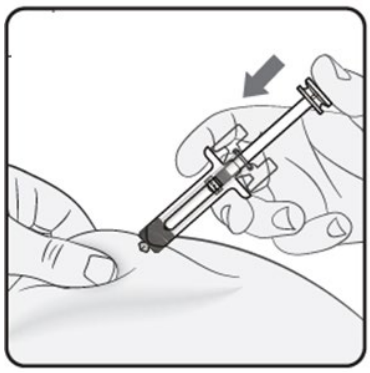


Step 3. Insert needle
Gently pinch the skin at the injection site and hold the pinch throughout the injection. With the other hand insert the needle into the skin at an angle of approximately 45 degrees as shown.

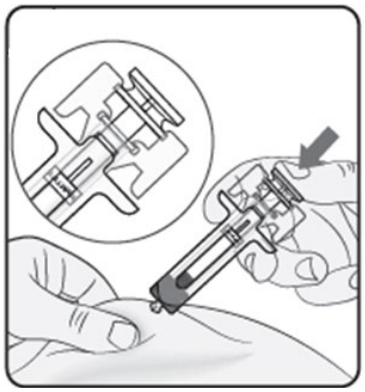


Step 4. Start injection
Continue to pinch the skin. Slowly press the plunger **as far as it will go**. This will make sure that a full dose is injected.

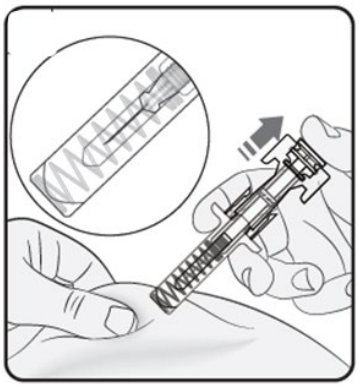
Note: If you cannot depress the plunger following insertion of the needle, use a new pre-filled syringe.



Step 5. Complete injection
Confirm that the plunger head is between the needle guard wings as shown. This will make sure that the needle guard has been activated and will cover the needle after the injection is finished.



Step 6. Release plunger
Keeping the pre-filled syringe at the injection site, slowly release the plunger until the needle is covered by the needle guard. Remove the pre-filled syringe from the injection site.



Step 7. Dispose of the pre-filled syringe
Dispose of the pre-filled syringe in accordance with local requirements.