LEQVIO® is for LDL-C reduction in patients with hypercholesterolemia along with diet and exercise.[1]

LEQVIO® (inclisiran) injection 284 mg/1.5 mL

Instructions for use for twice-yearly* HCP-administered LEQVIO®[1]

*After 2 initial doses.[1]

Product description

- No dose adjustments
- No refrigeration
- Shelf life of 3 years[2†]
- Single-dose prefilled syringe[1]
- No required post-injection–related safety monitoring

Not actual size. 27 gauge, ½-inch needle.[3]

Remember: Do not remove the needle cap until you are ready to inject LEQVIO.

†Always check the expiration date on the prefilled syringe before administration.

INDICATION

LEQVIO (inclisiran) injection is indicated as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH).

IMPORTANT SAFETY INFORMATION

LEQVIO is contraindicated in patients with a prior serious hypersensitivity reaction to inclisiran or any of the excipients in LEQVIO. Serious hypersensitivity reactions have included angioedema. Adverse reactions in clinical trials (≥3% of patients treated with LEQVIO and more frequently than placebo) were injection site reaction, arthralgia, and bronchitis.

Please click here for LEQVIO full Prescribing Information.

Instructions for Use: LEQVIO® injection for *subcutaneous* use[1]

(284 mg/1.5 mL single-dose prefilled syringe)

LEQVIO® (inclisiran) injection 284 mg/1.5 mL

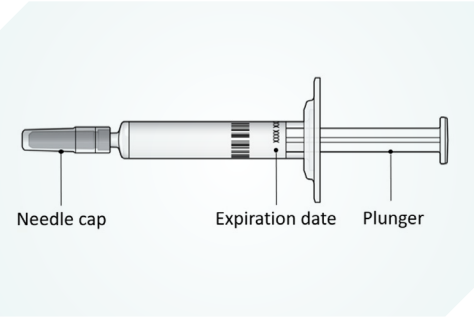
Important information you need to know before injecting LEQVIO:

- **Do not** use the prefilled 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 prefilled syringe has been dropped after removing the needle cap
- **Do not** try to reuse or take apart the prefilled syringe

1 Inspect the prefilled syringe

It should appear clear and colorless to pale yellow. **Do not** use if particulate matter or discoloration is seen. You may see air bubbles in the liquid, which is normal. **Do not** try to remove the air.

- **Do not** use the prefilled syringe if it looks damaged or if any of the solution for injection has leaked out of the prefilled syringe
- **Do not** use the prefilled syringe after the expiration date (EXP), which is printed on the prefilled syringe label and carton



2 Select and prepare the injection site

- Choose an injection site in the abdomen, upper arm, or thigh (**see Figure A**). **Do not** inject in areas of active skin disease or injury, such as sunburns, skin rashes, inflammation, or skin infection.
- Wipe the skin with an alcohol swab. Let the injection site dry before you inject the dose.

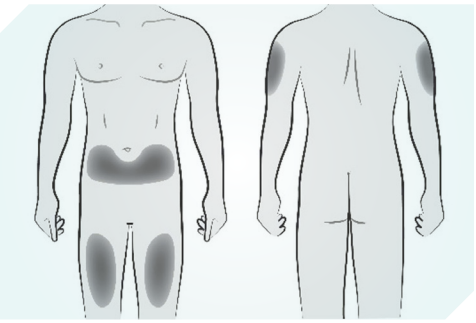


Figure A

IMPORTANT SAFETY INFORMATION

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3 Remove needle cap

Firmly pull straight to remove the needle cap from the prefilled syringe (**see Figure B**). 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.*

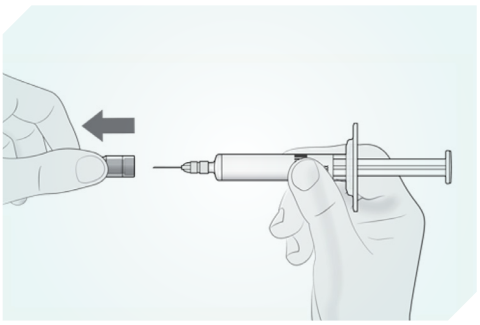

Figure B

4 Insert the 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 (**see Figure C**).

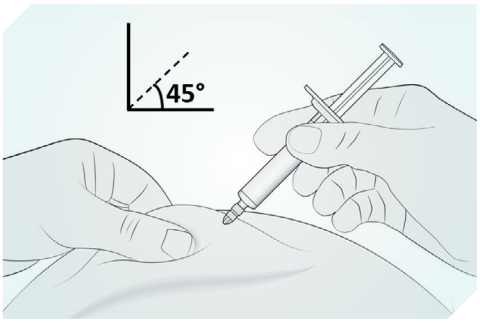

Figure C

5 Inject

Continue to pinch the skin. Slowly press the plunger **as far as it will go** (**see Figure D**). 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 prefilled syringe.

6 Complete injection and dispose of the prefilled syringe

Remove the prefilled syringe from the injection site. **Do not** put the needle cap back on. Dispose of the prefilled syringe in an FDA-cleared sharps disposal container right away after use.

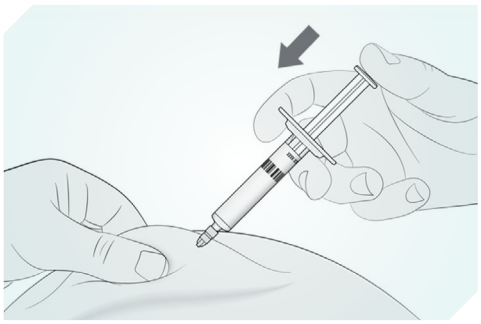

Figure D

Well tolerated with a proven safety profile[1]

Most Common Adverse Reactions[a,b]	LEQVIO® (n=1833) %	Placebo (n=1822) %
Injection site reaction[c]	8	2
Arthralgia	5	4
Bronchitis	4	3

2.5% of patients discontinued LEQVIO vs 1.9% with placebo

Injection site reactions were the most common causes for treatment discontinuation (0.2% of patients taking LEQVIO vs 0% taking placebo)

[a] Occurring in ≥3% of patients treated with LEQVIO and more frequently than placebo in Phase III clinical trials over 18 months.[1]
[b] The majority of adverse events were mild to moderate in severity.[4,5]
[c] Includes related terms such as injection site pain, erythema, and rash.[1]

Need additional support with LEQVIO administration?

If you need to replace LEQVIO syringes or have additional medical or technical questions, please contact the Novartis Customer Interaction Center at **1-888-NOW-NOVA (1-888-669-6682)**.

Visit **LEQVIOhcp.com** for more information.

References: 1. Leqvio. Prescribing information. Novartis Pharmaceuticals Corp. **2.** Data on file. LEQVIO 3-Year Shelf Life. Novartis Pharmaceuticals Corp; 2022. **3.** Data on file. LEQVIO Container Closure System. Novartis Pharmaceuticals Corp; 2022. **4.** Data on file. Novartis Pharmaceuticals Corp; 2019. **5.** Wright RS, Koenig W, Landmesser U, et al. Pooled safety analysis of inclisiran in 3,576 patients with approximately 10,000 person years of exposure from 7 trials. *J Am Coll Cardiol.* 2023;81(suppl A):1626. doi:10.1016/S0735-1097(23)02070-3

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