LEQVIO®
inclisiran

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YOUR GUIDE TO LEQVIO®

Time to target is critical in LDL-C management[1,2]

LEQVIO® delivers early, effective and sustained LDL-C control in secondary prevention[3-5]

LDL-C reduction was seen as soon as Day 90 and was sustained with just two maintenance injections a year, after initial and loading dose.*[3-5]

LEQVIO® is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:[5]

- 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

Adverse events should be reported. Reporting forms and information can be found at **http://www.mhra.gov.uk/yellowcard**. Adverse events should also be reported to Novartis online through the pharmacovigilance intake (PVI) tool at **www.novartis.com/report** or alternatively email medinfo.uk@novartis.com or call 01276 698370.

* The baseline mean ± SD LDL-C levels in ORION-10 were 2.70 ± 1.02 mmol/L with LEQVIO® and 2.71 ± 0.96 mmol/L with placebo.[3]

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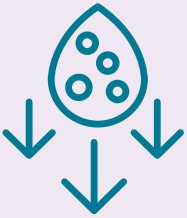
What is LEQVIO®?



LEQVIO® is an HCP-administered subcutaneous injection[5] that lowers LDL-C by **~50%** from baseline in as little as 3 months, and maintains it between **6-monthly injections*** in patients on maximally tolerated statin.[3]

No dose adjustments required[5]

No refrigeration required[5]

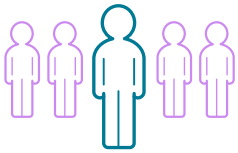
No additional blood monitoring mandated†[5]

Can be administered during existing appointments

* After an initial dose, LEQVIO® is administered again at 3 months, followed by every 6 months.[5]
† Beyond what is already clinically indicated.

Why lower lipids?

Long-term exposure to persistently high LDL-C can cause ASCVD and associated CV events[1]



Nearly 1 in 5 (18.3%) patients who suffer an MI experience another CV event within 1 year†[6]

Each 1 mmol/L LDL-C reduction is associated with a **22% relative risk reduction in MACE** (RR=0.78, 95% CI: 0.76 to 0.80)§[7]

The effect of LEQVIO® on CV morbidity and mortality has not yet been determined.[5]

‡ Based on a retrospective cohort study of patients with primary MI between July 2006 and June 2011 from Swedish national registries. The MI population consisted of 97,254 patients who were alive 1 week after discharge.[6]

§ Based on a meta-analysis of data from randomised statin trials over an average of 4.9 years (N=169,138). MACE include fatal MI or fatal stroke.[7]

LEQVIO® recommendations in the UK

LEQVIO® is recommended by NICE[8]

LEQVIO® is recommended as an option for treating primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia as an adjunct to diet in adults. It is recommended only if:[8]

1 **there is a history of any of the following cardiovascular events:**

- acute coronary syndrome (such as myocardial infarction or unstable angina needing hospitalisation)
- coronary or other arterial revascularisation procedures
- coronary heart disease
- ischaemic stroke or
- peripheral arterial disease, and

1 **low-density lipoprotein cholesterol (LDL-C) concentrations are persistently 2.6 mmol/L or more, despite maximum tolerated lipid-lowering therapy**, that is:

- maximum tolerated statins with or without other lipid-lowering therapies or,
- other lipid-lowering therapies when statins are not tolerated or are contraindicated

LEQVIO® is accepted for restricted use by SMC[9]

LEQVIO® is accepted for use within NHS Scotland, within its licensed indication, for specialist use only in patients at high cardiovascular risk as follows:[9]

- Patients with **heterozygous familial hypercholesterolaemia (HeFH) and LDL-C ≥5.0 mmol/L for primary prevention** of cardiovascular events or,
- Patients with **HeFH and LDL-C ≥3.5 mmol/L for secondary prevention** of cardiovascular events or,
- Patients at high risk due to **previous cardiovascular events and LDL-C ≥4.0 mmol/L** or,
- Patients with **recurrent/polyvascular disease and LDL-C ≥3.5 mmol/L**

LEQVIO® is also accepted for use in Northern Ireland[10] and recommended by the AWMSG in Wales[11] for the same reimbursed population as the SMC

LEQVIO® efficacy and safety data

Effective

LDL-C reduction of

52%

from baseline vs placebo in patients on maximally tolerated statin*[3]

Sustained

Maintained LDL-C reductions from baseline between

6-monthly

maintenance doses up to Day 540*[3]

Generally well tolerated

Injection site reactions (8.2%) are the only reported treatment-associated adverse reactions[5]

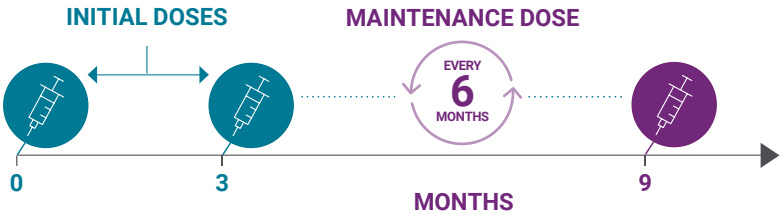
* In ORION-10, the baseline mean ± SD LDL-C levels were 2.70 ± 1.02 mmol/L with LEQVIO® and 2.71 ± 0.96 mmol/L with placebo. At Month 17, LEQVIO® delivered placebo-corrected LDL-C reductions of 52.3%, as compared with baseline (-51.3% with LEQVIO® vs +1.0% with placebo; 95% CI: -55.7 to -48.8; p<0.001; co-primary endpoint), with a time-adjusted LDL-C reduction of 53.8% (-51.3% with LEQVIO® vs +2.5% with placebo; 95% CI: -56.2 to -51.3; p<0.001) from baseline between Months 3 and 18 relative to placebo (co-primary endpoint).[3]

LEQVIO® dosing and administration

Subcutaneous administration of LEQVIO®[5]

The recommended dose of LEQVIO® is 284 mg administered as a single subcutaneous injection: initially, again at 3 months, followed by every 6 months.[5]

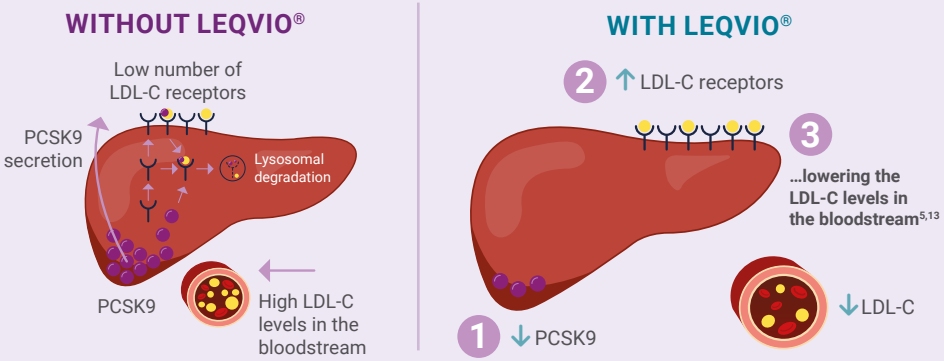
LEQVIO® is administered by an HCP,[5] supporting treatment adherence.



For full information on LEQVIO® dosing and administration, please refer to the SmPC.

Mechanism of action

1 LEQVIO® **works differently from other lipid-lowering therapies** by preventing the production of PCSK9 in the liver[5,12,13]



What makes LEQVIO® innovative?

Instead of blocking circulating PCSK9, LEQVIO®, as an siRNA therapy, interferes with the RNA that codes for this protein, reducing its production in the first place[5,13]

LEQVIO® commercial agreement (England only)

The LEQVIO® commercial agreement supports implementation in general practice[14]

The enhanced NHS England Commercial Agreement for LEQVIO®:[14]

- **Reimbursement supplement of £15** to support LEQVIO® implementation
- **No discount deductions** ('clawback')
- **Net income of up to ~£17.40 per injection** for general practice providers

Reimbursement supplement		Dispensing fee		Net income per injection
£15 (Reimbursement of £60 minus a nominal charge of £45)	+	Up to **~£2.40**	=	Up to **~£17.40**

What does the commercial agreement mean for secondary care?

LEQVIO® is fully reimbursed by NHS England, with no impact on secondary care budgets:[14]

- Full reimbursement will depend on the provision of accurate data submitted through existing systems[14]

Make LEQVIO® your first-choice post statins to reduce LDL-C in secondary prevention patients with an LDL-C ≥2.6 mmol/L

The effect of LEQVIO® on CV morbidity and mortality has not yet been determined.[5]

Notes

ASCVD – atherosclerotic cardiovascular disease; AWMSG – All Wales Medicines Strategy Group; CI – confidence interval; CV – cardiovascular; HCP – healthcare professional; LDL-C – low-density lipoprotein cholesterol; MACE – major adverse cardiovascular events; MI – myocardial infarction; NICE – National Institute for Health and Care Excellence; PCSK9 – proprotein convertase subtilisin/kexin type 9; RNA – ribonucleic acid; RR – relative risk; SD – standard deviation; siRNA – small interfering ribonucleic acid; SMC – Scottish Medicines Consortium; SmPC – Summary of Product Characteristics

References: 1. Ference B et al. *Eur Heart J* 2017;38:2459-2472; **2.** Schubert J et al. *Eur Heart J* 2024;45:4204-4215; **3.** Ray KK et al. *N Engl J Med* 2020;382:1507-1519; **4.** Wright RS et al. *Cardiovasc Res* 2024;120:1400-1410; **5.** LEQVIO® Summary of Product Characteristics; **6.** Jernberg T et al. *Eur Heart J* 2015;36:1163-1170; **7.** Cholesterol Treatment Trialists' (CTT) Collaboration. *Lancet* 2010;376:1670-1681; **8.** NICE. https://www.nice.org.uk/guidance/ta733 [Accessed December 2025]; **9.** SMC. https://scottishmedicines.org.uk/medicines-advice/inclisiran-leqvio-full-smc2358/ [Accessed December 2025]; **10.** NI Formulary. https://niformulary.hscni.net/managed-entry/managed-entry-decisions/ [Accessed December 2025]; **11.** NHS Wales. https://awttc.nhs.wales/files/appraisals-asar-far/final-recommendation-inclisiran-leqvio-3746/ [Accessed December 2025]; **12.** Lamb YN. *Drugs* 2021;81:389-395; **13.** Nordestgaard BG et al. *Nat Rev Cardiol* 2018;15:261-272; **14.** NHS England. www.england.nhs.uk/long-read/funding-supply-inclisiran-leqvio [Accessed December 2025]

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