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Leqvio - Home - HCP

Prescribing information

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LEQVIO® is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:¹

- 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 statinintolerant, or for whom a statin is contraindicated.

For full safety information, please refer to the LEQVIO® Summary of Product Characteristics.

LEQVIO®▼ (inclisiran)

LEQVIO® is recommended by NICE, within its licensed indication, as an option for the treatment of eligible adult patients who:²

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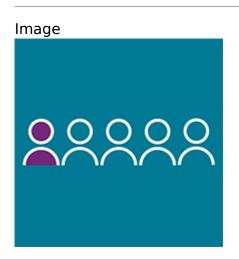


Have already had certain cardiovascular events (acute coronary syndrome such as MI or unstable angina needing hospitalisation, coronary or other arterial revascularisation procedures, coronary heart disease, ischaemic stroke or PAD)

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Have persistently elevated LDL-C levels (≥2.6 mmol/L) despite maximum tolerated statins with or without other lipid-lowering therapies, or other lipid-lowering therapies when statins are not tolerated or are contraindicated



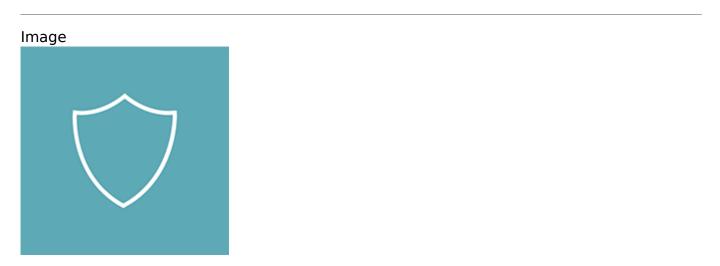
Nearly 1 in 5 patients with cardiovascular disease do not have a

recorded current prescription of lipid-lowering therapy, remaining at high risk for cardiovascular events and death $(n=472,650)^{*^3}$

The effect of LEQVIO $\mbox{\ensuremath{\mathbb{B}}}$ on cardiovascular morbidity and mortality has not yet been determined.¹



On average, LDL-C levels were reduced by ~50% from baseline (2.92±1.2 mmol/L) in eligible patients with ASCVD on LEQVIO® and a maximally tolerated statin in an observational study, which is consistent with the placebo-corrected results seen in the Phase III trials ORION-9, ORION-10 and ORION-11⁴⁻⁷



In clinical trials, LEQVIO® had a safety profile similar to placebo, apart from injection-site reactions (8.2% and 1.8% of patients, respectively)¹

*National CVDPREVENT data covering the period up to March 2022. Data was received from 96.6% of GP practices, including approximately 18 million patients.³

ASCVD, atherosclerotic cardiovascular disease; GP, general practitioner; LDL-C, low-density lipoprotein cholesterol; NICE, National Institute for Health and Care Excellence.

References

- 1. LEQVIO® Summary of Product Characteristics.
- 2. National Institute for Health and Care Excellence. Inclisiran for treating primary hypercholesterolaemia or mixed dyslipidaemia. Available at: <u>https://www.nice.org.uk/guidance/ta733/resources/inclisiran-for-</u>

treating... [Accessed January 2025].

- 3. Healthcare Quality Improvement Partnership. <u>https://www.hqip.org.uk/resource/third-annual-report-</u> <u>cvdprevent/</u> [Accessed January 2025].
- 4. Wright RS, et al. Oral presentation. ORION-8: Long-term efficacy and safety of twiceyearly inclisiran in high cardiovascular risk patients. ESC Congress 2023. Amsterdam, The Netherlands, 25–28 August 2023.
- 5. Raal FJ, et al. N Engl J Med 2020;382:1520-1530.
- 6. Ray KK, et al. N Engl J Med 2020;382:1507-1519.
- 7. Ray KK, et al. *Eur Heart J* 2022;43(48):5047–5057.

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

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