LEQVIO®▼
inclisiran

ORDERING AND REIMBURSEMENT IN ENGLAND: 'HOW TO' GUIDE

LEQVIO®▼ (inclisiran) 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.[1]

LEQVIO® is funded through a central NHS budget and reimbursement claims are submitted via the **FP34 (FP34PD/FP34D) route.**[2,3] Please ensure a **FP10** is submitted alongside this.

The FP34 form is used to send claims for **personally administered items**.[2]

To order LEQVIO®, the practice is required to have an AAH account. If you do not have an account, you can **open one online here**.

Please note that Novartis has no control over the content of the linked websites provided in this document.

LEQVIO® is considered a personally administered item and can be ordered for **same or next day delivery directly from AAH** (using AAH Point or your PMR system) with the codes below:[2]

Product Name	EAN Code	PIP Code
Inclisiran (Leqvio®)	7613421044237	4174751

LEQVIO® is **ordered at a cost of £45 (nominal charge)** per pre-filled syringe **plus VAT**[2,3] (nominal charge is the amount that primary care providers and community pharmacy pay for LEQVIO® and can access from the wholesaler)

A decision to start LEQVIO® is taken, according to NICE guidance,[4] and LEQVIO®, as an injectable treatment, is administered by a healthcare professional[1,3]

Complete FP10 and submit alongside the monthly **FP34 submission form** (done by the practice team at the end of the month) to the NHSBSA for **reimbursement at the Drug Tariff price of £50 plus VAT.** A VAT allowance is added to payment claims to recognise this incurred cost.[2]

For more information on sending in your claim to the NHSBSA, click here

LEQVIO® can also be supplied by the Community Pharmacy route by issuing an FP10 only (patients will need to pay a prescription fee, if they normally do so).[3]

For more information on which form to use, visit here

If you need any support, you can contact AAH Customer Care on 0344 5618899 or live chat with an agent via AAH Point from 9am–5pm Monday to Friday.

Novartis is unable to advise on VAT claims.

Prescribing information and adverse event reporting information are available overleaf

Funding for LEQVIO® is available in secondary care via a separate route.
Please contact Novartis for more information.

PRESCRIBING INFORMATION

Great Britain Prescribing Information: LEQVIO®▼ (inclisiran) Important note: Before prescribing, consult the Summary of Product Characteristics (SmPC). Presentation: Pre-filled syringe containing inclisiran sodium equivalent to 284 mg inclisiran in 1.5 ml solution. **Indication(s):** 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. **Dosage and administration:** 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:* No dose adjustment required for patients with mild or moderate hepatic impairment, mild, moderate or severe renal impairment or end-stage renal disease (use with caution in severe renal impairment) or elderly patients. *Administration:* Subcutaneous injection into abdomen (alternatively, 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. Inclisiran is intended for administration by a healthcare professional. **Contraindications:** Hypersensitivity to active ingredient or any of the excipients. **Warnings/Precautions:** *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. **Interactions:** Inclisiran is not a substrate for common drug transporters and, although in *vitro* studies were not conducted, it is not anticipated to be a substrate for cytochrome P450. Inclisiran is not an inhibitor or inducer of cytochrome P450 enzymes or common drug transporters. Therefore, inclisiran is not expected to have clinically significant interactions with other medicinal products. Based on the limited data available, clinically meaningful interactions with atorvastatin, rosuvastatin or other statins are not expected. **Fertility, pregnancy and lactation:** *Pregnancy:* No or limited data available from the use of inclisiran in pregnant women. Animal studies do not indicate any harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of inclisiran during pregnancy. *Breast feeding:* It is unknown whether inclisiran is excreted in human milk. Data in animals have shown excretion of inclisiran in milk. A risk to newborns/infants cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from inclisiran therapy, taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman. *Fertility:* No data on the effect of inclisiran on human fertility are available. Animal studies did not show any effects on fertility. **Undesirable effects:** Common (≥1/100 to <1/10): adverse reactions at injection site including site reaction, pain, erythema and rash. All reactions were mild or moderate in severity, transient and resolved without sequelae. *Other Adverse Effects:* Please consult the Summary of Product Characteristics for a detailed listing of all adverse events before prescribing. **Legal classification:** POM **Marketing Authorisation (MA) number, quantities and price:** PLGB 00101/1202 Leqvio 284mg pre-filled syringe £1987.36 (ex. VAT) per pack (1 pre-filled syringe). **Date of last revision of prescribing information:** October 2022 (ID 244658) Full Prescribing Information available from: Novartis Pharmaceuticals UK Limited, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, W12 7FQ. Telephone: (01276) 692255.

Adverse Event Reporting:
Adverse events should be reported. Reporting forms and information can be found at https://www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novartis via uk.patientsafety@novartis.com or online through the pharmacovigilance intake (PVI) tool at www.report.novartis.com

If you have a question about the product, please contact Medical Information on 01276 698370 or by email at medinfo.uk@novartis.com

Northern Ireland Prescribing Information: LEQVIO®▼ (inclisiran) Important note: Before prescribing, consult the Summary of Product Characteristics (SmPC). Presentation: Pre-filled syringe containing inclisiran sodium equivalent to 284 mg inclisiran in 1.5 ml solution. **Indication(s):** 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. **Dosage and administration:** 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:* No dose adjustment required for patients with mild or moderate hepatic impairment, mild, moderate or severe renal impairment or end-stage renal disease (use with caution in severe renal impairment) or elderly patients. *Administration:* Subcutaneous injection into abdomen (alternatively, 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. Inclisiran is intended for administration by a healthcare professional. **Contraindications:** Hypersensitivity to active ingredient or any of the excipients. **Warnings/Precautions:** *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. **Interactions:** Inclisiran is not a substrate for common drug transporters and, although in *vitro* studies were not conducted, it is not anticipated to be a substrate for cytochrome P450. Inclisiran is not an inhibitor or inducer of cytochrome P450 enzymes or common drug transporters. Therefore, inclisiran is not expected to have clinically significant interactions with other medicinal products. Based on the limited data available, clinically meaningful interactions with atorvastatin, rosuvastatin or other statins are not expected. **Fertility, pregnancy and lactation:** *Pregnancy:* No or limited data available from the use of inclisiran in pregnant women. Animal studies do not indicate any harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of inclisiran during pregnancy. *Breast feeding:* It is unknown whether inclisiran is excreted in human milk. Data in animals have shown excretion of inclisiran in milk. A risk to newborns/infants cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from inclisiran therapy, taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman. *Fertility:* No data on the effect of inclisiran on human fertility are available. Animal studies did not show any effects on fertility. **Undesirable effects:** Common (≥1/100 to <1/10): adverse reactions at injection site including site reaction, pain, erythema and rash. All reactions were mild or moderate in severity, transient and resolved without sequelae. *Other Adverse Effects:* Please consult the Summary of Product Characteristics for a detailed listing of all adverse events before prescribing. **Legal classification:** POM. **Marketing Authorisation (MA) number, quantities and price:** EU/1/20/1494/001 Leqvio 284mg pre-filled syringe £1987.36 (ex. VAT) per pack (1 pre-filled syringe); EU/1/20/1494/002 Leqvio 284mg pre-filled syringe with needle guard £1987.36 (ex. VAT) per pack (1 pre-filled syringe). **Date of last revision of prescribing information:** October 2022 (ID 244660) **Full Prescribing Information available from:** Novartis Pharmaceuticals UK Limited, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, W12 7FQ. Telephone: (01276) 692255.

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AAH – All About Health; EAN – European Article Number; LDL-C – low-density lipoprotein cholesterol; NHS – National Health Service; NHSBSA – National Health Service Business Services Authority; NICE – National Institute for Health and Care Excellence; PIP – Pharmacists Interface Product; PMR – patient medication record; VAT – value added tax

REFERENCES

1. LEQVIO® Summary of Product Characteristics.
2. NHS. Summary information on the funding and supply of inclisiran (Leqvio®). https://www.england.nhs.uk/aac/wp-content/uploads/sites/50/2023/04/B1913_Summary-information-on-the-funding-and-supply-of-inclisiran_v3_June-2023.pdf [Accessed July 2023].
3. AAC. Implementing inclisiran (Leqvio®) into the lipid management pathway. A toolkit for a population health management approach to adopting innovation. September 2021.
4. NICE. NICE Guidance for LEQVIO®. https://www.nice.org.uk/guidance/ta733/resources/inclisiran-for-treating-primary-hypercholesterolaemia-or-mixed-dyslipidaemia-pdf-82611252825541 [Accessed July 2023].

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