

PRODUCT INFORMATION

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
- The **recommended dose of inclisiran (Leqvio[®]) is 284 mg** administered in 1.5 mL solution in a pre-filled syringe¹
 - **Shelf life:** 3 years¹
 - Inclisiran does not require any special storage conditions. Do not freeze¹

WHEN TO INJECT

After an initial dose, inclisiran is administered again at 3 months, followed by a dose every 6 months.¹



HOW AND WHERE TO INJECT

Inclisiran is a single-use subcutaneous injection for administration by a healthcare professional.¹



STEP 1: INSPECT THE SYRINGE

- Check the inclisiran solution for injection visually before administration – it should be clear, colourless to pale yellow and essentially free of particles¹



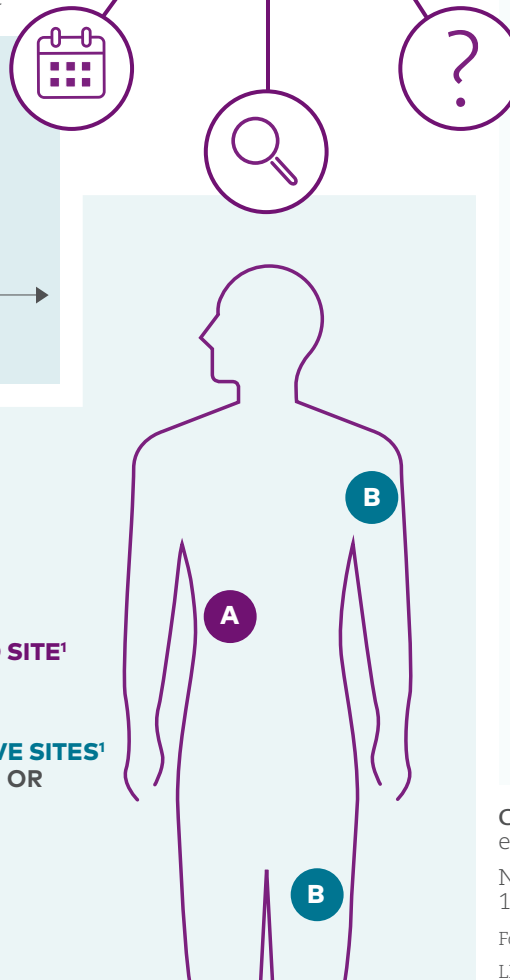
AREAS TO AVOID

Areas of active skin disease or injury (e.g. sunburns, skin rashes, inflammation or skin infections)¹

STEP 2: INJECT

- A PREFERRED SITE¹ ABDOMEN**
- B ALTERNATIVE SITES¹ UPPER ARM OR THIGH**

'HOW TO' GUIDE



MANAGING MISSED DOSES

PLANNED DOSE MISSED BY <3 MONTHS	Administer inclisiran and continue dosing as per patient's original schedule ¹
PLANNED DOSE MISSED BY >3 MONTHS	Start new dosing schedule: initial dose, second dose at 3 months, followed by a dose every 6 months ¹

DOSING IN SPECIAL POPULATIONS

ELDERLY (AGE ≥65 YEARS)		No dose adjustment¹
HEPATIC IMPAIRMENT		No dose adjustment: mild (Child-Pugh class A) or moderate (Child-Pugh class B) ¹ Use with caution as no data available: severe (Child-Pugh class C) ¹
RENAL IMPAIRMENT		No dose adjustment: mild, moderate or severe, or end-stage renal disease ¹ Use with caution due to limited experience: severe ¹ Haemodialysis should not be performed for at least 72 hours after inclisiran dosing ¹
PREGNANCY/BREASTFEEDING		Avoid use during pregnancy as no data available ¹ Decide whether to discontinue breastfeeding or to discontinue/abstain from inclisiran as a risk to newborns/infants cannot be excluded ¹

INJECTION DO'S AND DON'TS

	Keep inclisiran out of the sight and reach of children ²		Do not use inclisiran if it contains visible particulate matter or after the expiry date ¹²
	Dispose of unused medicine or any waste material in accordance with local requirements ¹		In the absence of compatibility studies, inclisiran must not be mixed with other medicinal products ¹

Contraindications: hypersensitivity to the active substance or to any of the excipients listed in section 6.1 of the **Summary of Product Characteristics**¹

No data are available for the use of inclisiran in children aged under 18 years.¹

For further information please refer to the **Summary of Product Characteristics**.

LDL-C – low-density lipoprotein cholesterol

Prescribing information and adverse event reporting information are available overleaf

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 ($\geq 1/100$ 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 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)

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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.

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Undesirable effects: Common ($\geq 1/100$ 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.

Adverse Event Reporting:

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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

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References

1. Leqvio® Summary of Product Characteristics.
2. Leqvio® Patient Information Leaflet.