United Kingdom 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.

I**ndication(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: January 2025 (ID FA-11329827)

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 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 online through the pharmacovigilance intake (PVI) tool at www.novartis.com/report or alternatively email medinfo.uk@novartis.com or call 01276 698370.