# Inclisiran ▼ (Leqvio®) Information

Background

Inclisiran is a new lipid lowering drug with a novel mode of action. It is a small interfering RNA (siRNA) drug, which directs the catalytic breakdown of mRNA responsible for producing the PCSK9 protein. PCSK9 directs the degradation of LDL-C receptors. Therefore, by reducing PCSK9 production, inclisiran increases LDL-C receptor expression on the hepatocyte cell surface, which increases LDL-C uptake and thereby lowers LDL-C levels in the circulation (typically by around 50%).

Trials are currently underway to obtain CVD clinical outcome data. NICE approval was based on the assumption that the lipid lowering effect of inclisiran will result in significant CVD clinical benefits.

Indications

Inclisiran has been approved by NICE TA733 for adults (≥18 years) with:

1. History of cardiovascular disease i.e. any of the following
   - coronary heart disease
   - ischaemic stroke
   - peripheral arterial disease

*AND*

2. LDL-C persistently ≥2.6 mmol/L despite maximum tolerated lipid-lowering therapy

Gloucestershire Joint Formulary Status

Inclisiran is listed as a 'green' drug on the Gloucestershire Joint Formulary. Primary Care prescribers may initiate inclisiran in line with the Gloucestershire Lipid Pathway.

Primary Care prescribers may also initiate inclisiran on the advice of a lipid lowering Specialist.

Contraindications / precautions

Hypersensitivity to inclisiran or any of the excipients.
Haemodialysis should not be performed for at least 72 hours after inclisiran dosing.
Use with caution in severe hepatic impairment (Child-Pugh class C) – no data available.
Avoid in pregnancy / breastfeeding.

Adverse effects / Interactions

In clinical trials, the only adverse effects associated with inclisiran were injection site reactions (e.g. pain, erythema, rash) which were mild to moderate, transient and resolved without sequelae.

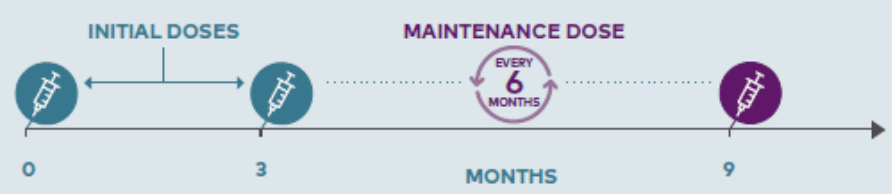
As inclisiran is classed as an MHRA black triangle ▼drug, any suspected adverse reactions should be reported via the Yellow Card Scheme.

No known drug interactions.

## Dose

Inclisiran 284mg (pre-filled syringe) administered as a subcutaneous injection into the abdomen (preferred) or upper arm or thigh.

After the initial dose, inclisiran is administered again at 3 months, followed by a dose every 6 months thereafter:




## Missed doses

Planned dose missed by less than 3 months: Administer inclisiran and continue as per original dosing schedule.

Planned dose missed by more than 3 months: Start new dosing schedule i.e. initial dose, second dose at 3 months, followed by a dose every 6 months.

## Monitoring

No specific monitoring required. LDL-C should be re-checked 8 weeks after the 2nd dose.
All patients should have an annual cardiovascular disease review. Patients should be asked to report any suspected adverse effects.

## Prescribing / Ordering

Inclisiran should be ordered directly to the GP practice (£45 per pre-filled syringe) by calling the AAH customer care team on 0344 561 8899.

Inclisiran should be administered by the GP practice and added to the FP34D submission to NHS BSA (done by the practice team at the end of each month). The GP practice will be reimbursed at the NHS discounted drug tariff price of £60. The difference between the purchase price the NHS reimbursement price (i.e. £15) represents an injection administration and handling fee. A GP practice will not be paid this fee if they obtain inclisiran from a pharmacy.

## Storage / Shelf-life

No special storage conditions (do not freeze). Shelf-life = 3 years.

## Inclisiran Patient Booklet

A patient's guide to inclisiran may be downloaded via the following link:
https://www.pro.novartis.com/uk-en/sites/pro_novartis_com_uk/files/2025-01/inclisiran-patient-leaflet.pdf