DOSING AND ADMINISTRATION:

LEQVIO®▼ inclisiran

PRODUCT INFORMATION

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

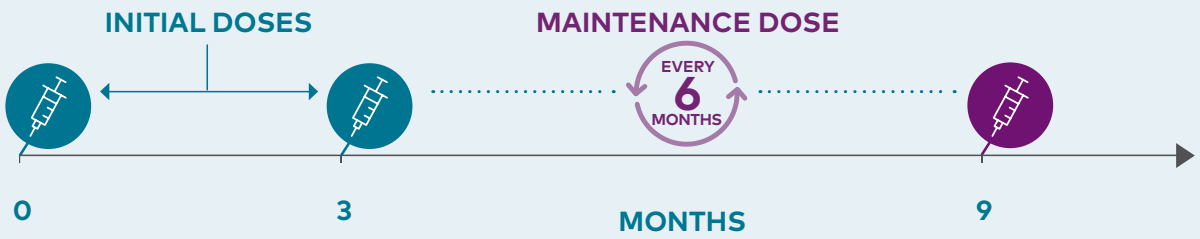
- in combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin, or
- alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.[1]

- The **recommended dose of LEQVIO is 284 mg** administered in 1.5 mL solution in a pre-filled syringe[1]
- **Shelf life:** 3 years[1]
- LEQVIO does not require any special storage conditions. Do not freeze[1]

'HOW TO' GUIDE

WHEN TO INJECT

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



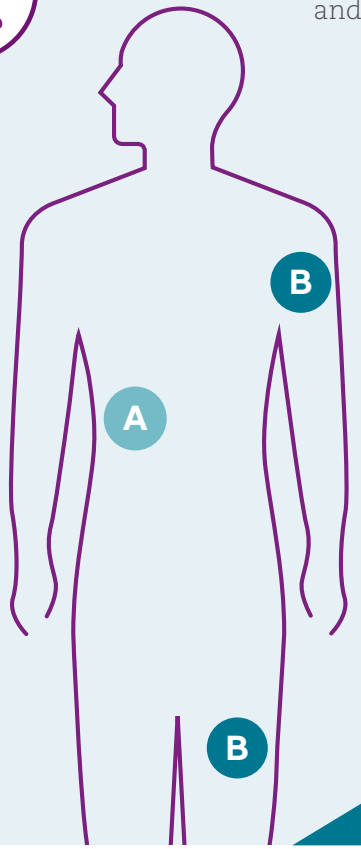
HOW AND WHERE TO INJECT

LEQVIO is a single-use subcutaneous injection **for administration by a healthcare professional**.[1,2]

STEP 1: INSPECT THE SYRINGE

- Check the LEQVIO solution for injection visually before administration – it should be clear, colourless to pale yellow and essentially free of particles[1]

STEP 2: INJECT



A PREFERRED SITE[1]
ABDOMEN

B ALTERNATIVE SITES[1]
UPPER ARM OR THIGH

AREAS TO AVOID

Areas of active skin disease or injury (e.g. sunburns, skin rashes, inflammation or skin infections)[1,2]

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

Scan or click (if viewing digitally) **the QR code to view the Prescribing Information**

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In placebo-controlled clinical trials, LEQVIO had a generally well-tolerated safety profile, apart from injection site reactions (8.2% and 1.8% of patients, respectively).[1]

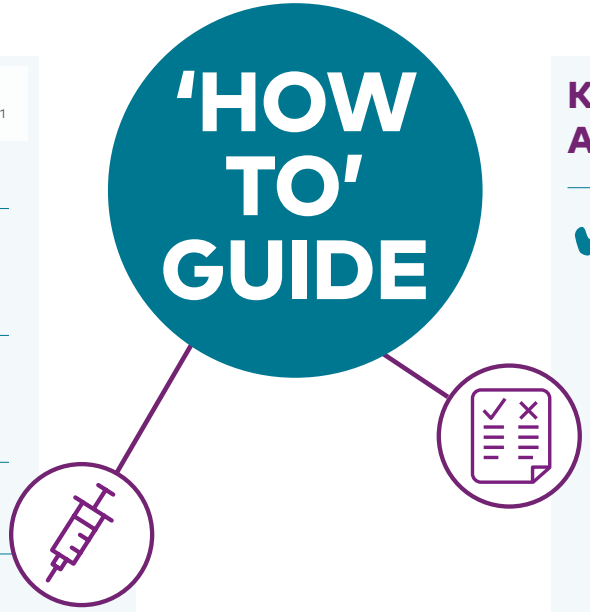
MANAGING MISSED DOSES

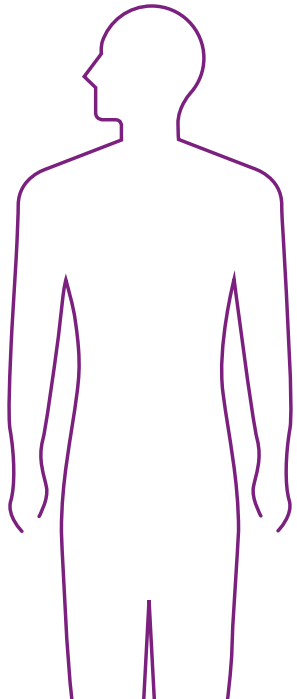
PLANNED DOSE MISSED BY **<3 MONTHS**	Administer LEQVIO and continue dosing as per patient's original schedule[1]
PLANNED DOSE MISSED BY **>3 MONTHS**	Start new dosing schedule: initial dose, second dose at 3 months, followed by a dose every 6 months[1]

DOSING IN SPECIAL POPULATIONS

ELDERLY (AGE ≥65 YEARS)	**No dose adjustment**[1]
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 LEQVIO dosing[1]
PREGNANCY/ BREASTFEEDING	**Avoid use during pregnancy** as no data available[1] **Decide whether to discontinue breastfeeding or to discontinue/abstain from LEQVIO** as a risk to newborns/ infants cannot be excluded[1]

'HOW TO' GUIDE





KEY INJECTION DO'S AND DON'TS

✓	✗
Keep LEQVIO out of the sight and reach of children[2]	Do not use LEQVIO if it contains visible particulate matter or after the expiry date[1,2]
Dispose of unused medicine or any waste material in accordance with local requirements[1]	In the absence of compatibility studies, LEQVIO 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.[1,2] For further information please refer to the **Summary of Product Characteristics.**[1]

LDL-C=low-density lipoprotein cholesterol

References

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

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