swissmedic

Summary report on authorisation dated 3 December 2024

Leqvio® (active substance: inclisiran)

Authorisation in Switzerland: 9 September 2021

Solution for injection for the treatment of adults with high LDL cholesterol, including those with heterozygous familial hypercholesteraemia or mixed dyslipidaemia, along with diet

About the medicinal product

Leqvio contains the active substance inclisiran and is used in adults with hypercholesteraemia (high cholesterol) or mixed dyslipidaemia (uncontrolled levels of lipids in the blood). It is used along with diet to lower cholesterol, either alone or in combination with other lipid-lowering therapies.

Leqvio is helpful for patients who require additional reduction in their LDL cholesterol if the maximum tolerable dose of a statin is not sufficient, or for patients who cannot tolerate statins, or for whom statins are contraindicated.

Statins are medicinal products that help to reduce cholesterol levels in the blood, thereby lowering the risk of cardiovascular disease.

Mode of action

Leqvio contains the active substance inclisiran which helps to lower the "bad" cholesterol (LDL cholesterol) in the blood. Inclisiran works by reducing the production of a protein called PCSK9.

LDL receptors are found on the surface of liver cells (hepatocytes). A protein called PCSK9 binds to these LDL receptors and triggers the breakdown of these receptors. As a result, the "bad" LDL cholesterol is not removed sufficiently from the blood. Leqvio restricts the production of the PCSK9 protein.

When less PCKS9 is produced, more of these receptors remain on the cell surface and can remove more LDL cholesterol from the blood, which in turn reduces cholesterol levels.

Administration

Leqvio is a prescription-only medicinal products and should be administered by healthcare professionals.

Leqvio is available as a solution for injection in a pre-filled syringe. Each pre-filled syringe

contains 1.5 mL solution with 284 mg inclisiran (equivalent to 300 mg inclisiran sodium). The recommended dose is 284 mg as a single subcutaneous injection at the start of treatment, with the same dose given again after 3 months and then every 6 months after that.

Efficacy

The efficacy of inclisiran was investigated in 3 studies (ORION-9, ORION-10, and ORION-11) in which a total of 3,655 patients participated.

The patients had atherosclerotic cardiovascular disease (ASCVD), an ASCVD risk equivalent, or heterozygous familial hypercholesteraemia.

The efficacy of Leqvio was investigated versus placebo (dummy drug).

In the ORION-9 study in patients with heterozygous familial hypercholesterolaemia (HeFH), Leqvio significantly reduced LDL cholesterol by 49.9% after 510 days versus placebo. In the ORION-10 study, which included patients with ASCVD, LDL cholesterol was reduced by 57.6% versus the baseline until Day 510. The ORION-11 study with patients who had ASCVD or ASCVD risk equivalents had similar results: a 53.5% reduction in LDL cholesterol in the same time period.

These results document the significant efficacy of Leqvio in the reduction of LDL cholesterol.

Precautions, undesirable effects, & risks

Leqvio must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most common undesirable effect was injection site reactions (8.2% of the subjects), most of which were mild and temporary.

It is important that patients with kidney disease or severe liver function disorders do not take this medication without close medical supervision.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

The need for treatment options for hypercholesteraemia and mixed dyslipidaemia remains high, as many patients have not reached the target LDL cholesterol levels despite the maximum tolerated statin dose, or cannot tolerate statins. Leqvio can meet this need, as it can be used in conjunction with diet and statins or on its own for patients with statin intolerance.

The aforementioned studies have shown that Leqvio significantly reduces LDL cholesterol levels and is well tolerated, with the most frequent side effects being mild and temporary. Therefore, the benefits outweigh the risks. Based on these findings, Swissmedic has authorised the medicinal product Leqvio, which contains the active substance inclisiran, in Switzerland for the treatment of hypercholesteraemia and mixed dyslipidaemia.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Leqvio®

Information for patients (package leaflet): Information for patients Leqvio®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

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