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Leqvio (*inclisiran*)

An overview of Leqvio and why it is authorised in the EU

What is Leqvio and what is it used for?

Leqvio is a medicine used to reduce cholesterol in the blood. It is used in adults with primary hypercholesterolaemia or mixed dyslipidaemia (conditions that cause high levels of fats, including cholesterol, in the blood). It should be used with a low-fat diet.

Leqvio is used in combination with a statin (a type of cholesterol-lowering medicine) when the maximum dose of the statin does not lower cholesterol levels enough. It can also be used in combination with other cholesterol-lowering medicines in patients who cannot take a statin.

Leqvio contains the active substance inclisiran.

How is Leqvio used?

Leqvio is given by injection under the skin, usually in the belly but also in the upper arm or thigh. After the first injection, the next dose is given after 3 months and then it is given every 6 months.

The medicine can only be obtained with a prescription. For more information about using Leqvio, see the package leaflet or contact your doctor or pharmacist.

How does Leqvio work?

Inclisiran, the active substance in Leqvio, interferes with RNA (genetic material) to limit the production of PCSK9, a protein that can increase levels of LDL-cholesterol ('bad' cholesterol). By preventing PCSK9 production, Leqvio helps to lower LDL-cholesterol levels.

What benefits of Leqvio have been shown in studies?

Three main studies involving a total of 3,660 patients found Leqvio effective at lowering levels of LDL-cholesterol. Over 94% of patients in the studies were also taking statins or other medicines to lower the levels of lipids (fats) in blood.

The studies included patients with a form of hypercholesterolaemia that runs in families and patients with raised LDL-cholesterol who either had atherosclerotic cardiovascular disease (where fatty deposits have built up in blood vessels) or were prone to atherosclerotic cardiovascular disease. After 510 days

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(around 15 months), the results were similar for all studies, and overall, LDL-cholesterol had dropped by over 50% in patients treated with Leqvio compared with those receiving placebo (a dummy treatment).

What are the risks associated with Leqvio?

The most common side effects with Leqvio (which may affect up to 1 in 10 people) are reactions such as pain, redness and rash at the injection site.

For the full list of side effects and restrictions of Leqvio, see the package leaflet.

Why is Leqvio authorised in the EU?

Studies have found worthwhile reductions in LDL-cholesterol levels in patients treated with Leqvio, which go beyond reductions attained with statins or other lipid-lowering medicines. There is no direct evidence yet that Leqvio reduces heart attacks or stroke but reduction in LDL-cholesterol is linked to reduction in atherosclerotic cardiovascular disease. The side effects of Leqvio are manageable.

The European Medicines Agency therefore decided that Leqvio's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Leqvio?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Leqvio have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Leqvio are continuously monitored. Side effects reported with Leqvio are carefully evaluated and any necessary action taken to protect patients.

Other information about Leqvio

Leqvio received a marketing authorisation valid throughout the EU on 09 December 2020.

Further information on Leqvio can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/leqvio.

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