10 November 2016
EMA/CHMP/706807/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Lusduna

insulin glargine

On 10 November 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Lusduna, intended for treatment of diabetes. The applicant for this medicinal product is Merck Sharp & Dohme Limited.

Lusduna will be available as a solution for injection (100 units/ml). The active substance of Lusduna is insulin glargine, a long-acting insulin analogue (ATC code: A10A E04). Insulin glargine binds specifically to the human insulin receptor and results in the same pharmacological effects as human insulin.

The expected benefit with Lusduna is its ability to lower high blood glucose. The most common side effects are hypoglycaemia, skin and allergic reactions and skin changes at the injection site.

Lusduna is a biosimilar medicinal product highly similar to the reference product Lantus. Studies have shown Lusduna to have comparable quality, safety and efficacy to the reference product Lantus.

The full indication is: "Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above."

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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