EUROPEAN MEDICINES AGENCY
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Public statement

Lusduna

Withdrawal of the marketing authorisation in the European Union

On 29 October 2018, the European Commission withdrew the marketing authorisation for Lusduna (insulin glargine) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Merck Sharp & Dohme B.V., which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Lusduna is a biosimilar medicine of Lantus. It was granted marketing authorisation in the EU on 4 January 2017 for treatment of diabetes mellitus. The product has never been marketed in the EU.

The European Public Assessment Report (EPAR) for Lusduna will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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