30 April 2020
EMA/CHMP/207078/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Insulin aspart Sanofi

insulin aspart

On 30 April 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Insulin aspart Sanofi, intended for the treatment of diabetes mellitus. The applicant for this medicinal product is sanofi-aventis groupe.

Insulin aspart Sanofi will be available as a solution for injection (100 units/ml). The active substance of Insulin aspart Sanofi is insulin aspart, a fast-acting insulin analogue (ATC code: A10AB04) which is absorbed more rapidly by the body and can therefore act faster than human insulin. The replacement insulin acts in the same way as naturally produced insulin; it works by facilitating uptake of glucose into skeletal muscle and fat tissue, and by inhibiting glucose output from the liver.

Insulin aspart Sanofi is a biosimilar medicinal product. It is highly similar to the reference product NovoRapid (insulin aspart), which was authorised in the EU on 7 September 1999. Data show that Insulin aspart Sanofi has comparable quality, safety and efficacy to NovoRapid (insulin aspart). More information on biosimilar medicines can be found here.

The full indication is:

"Insulin aspart Sanofi is indicated for the treatment of diabetes mellitus in adults, adolescents and children aged 1 year 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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