10 December 2020
EMA/CHMP/623370/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Kixelle

insulin aspart

On 10 December 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 Kixelle, intended for the treatment of diabetes mellitus.

The applicant for this medicinal product is Mylan IRE Healthcare Limited.

Kixelle will be available as a solution for injection (100 units/ml). The active substance of Kixelle is insulin aspart, a fast-acting insulin analogue (ATC code: A10AB05) 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.

Kixelle 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 Kixelle has comparable quality, safety and efficacy to NovoRapid. More information on biosimilar medicines can be found here.

The full indication is:

> Kixelle is indicated for 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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