24 February 2022
EMA/CHMP/113249/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Inpremzia

insulin human (rDNA)

Medicinal product no longer authorised

On 24 February 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Inpremzia, intended for the treatment of diabetes mellitus.

The applicant for this medicinal product is Baxter Holding B.V.

Inpremzia will be available as 1 IU/ml solution for infusion. The active substance of Inpremzia is insulin human (rDNA), a fast-acting human insulin for injection (ATC code: A10AB01) which lowers the blood glucose by facilitating uptake of glucose into muscle and fat cells and by simultaneously inhibiting glucose output from the liver.

Inpremzia is a biosimilar medicinal product. It is highly similar to the reference product Actrapid (human insulin), which was authorised in the EU on 7 October 2002. Data show that Inpremzia has comparable quality, safety and efficacy to Actrapid (human insulin). More information on biosimilar medicines can be found here.

The full indication is:

> Inpremzia is indicated for the treatment of diabetes mellitus.

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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