24 February 2022
EMA/CHMP/83437/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Truvelog Mix 30

insulin aspart

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 Truvelog Mix 30, intended for the treatment of diabetes mellitus.

The applicant for this medicinal product is sanofi-aventis groupe.

Truvelog Mix 30 will be available as a 100 U/ml suspension for injection. The active substance of Truvelog Mix 30 is insulin aspart, an intermediate- or long-acting insulin which is combined with fast-acting insulin and used in diabetes (ATC code: A10AD05). Insulin aspart lowers blood glucose by facilitating uptake of glucose into muscle and fat cells and by simultaneously inhibiting glucose output from the liver.

Truvelog Mix 30 is a biosimilar medicinal product. It is highly similar to the reference product NovoMix (insulin aspart), which was authorised in the EU on 1 August 2000. Data show that Truvelog Mix 30 has comparable quality, safety and efficacy to NovoMix (insulin aspart). More information on biosimilar medicines can be found here.

The full indication is:

> Truvelog Mix 30 is indicated for treatment of diabetes mellitus in adults, adolescents and children aged 10 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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union