22 April 2022
EMA/CHMP/223184/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion

Insulatard

insulin human

On 22 April 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion in accordance with Article 58 of Regulation (EC) No 726/2004[1] for the medicinal product Insulatard, intended for the treatment of diabetes mellitus. This medicinal product has been developed by Novo Nordisk A/S.

Insulatard will be available as 100 IU/ml suspension for injection. The active substance of Insulatard is insulin human, a human insulin for injection with gradual onset and long duration of action (ATC code: A10AC01), which lowers the blood glucose levels by facilitating uptake of glucose into muscle and fat cells and by simultaneously inhibiting glucose output from the liver.

The benefit of Insulatard is that it lowers blood glucose levels in patients with type 1 and type 2 diabetes and helps prevent long-term complications. The most common side effect is hypoglycaemia.

The full indication is:

> Insulatard is indicated for 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).

Insulatard has been authorised in the EU since 2002. The purpose of this application is to introduce updated storage conditions for Insulatard in order to further facilitate the use of the product in relevant countries outside the EU with challenging temperature conditions and limited access to refrigeration. Following the evaluation of the additional stability data submitted, the CHMP concluded to allow that Insulatard may be stored outside of the refrigerator at temperatures below 30°C for up to four weeks before opening.

Insulatard with added storage time outside a refrigerator is intended exclusively for markets outside the European Union.

[1] Scientific opinion in accordance with Article 58 of (EC) No Regulation 726/2004 in the context of cooperation with the World Health Organisation (WHO)

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