



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 April 2022
EMA/CHMP/223178/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion

Actrapid

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 726/2004¹ for the medicinal product Actrapid, intended for the treatment of diabetes mellitus. This medicinal product has been developed by Novo Nordisk A/S.

Actrapid will be available as a 100 IU/ml solution for injection. The active substance of Actrapid is insulin human, a fast-acting human insulin for injection (ATC code: A10AB01), 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 Actrapid 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:

Actrapid 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).

Actrapid has been authorised in the EU since 2002. The purpose of this application is to introduce updated storage conditions for Actrapid 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 Actrapid may be stored outside of the refrigerator at temperatures below 30°C for up to four weeks before opening.

Actrapid 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)

