28 March 2025
EMA/100240/2025
EMEA/H/C/006011

Withdrawal of application for the marketing authorisation of Insulin Human Rechon (insulin human)

Rechon Life Science AB withdrew its application for a marketing authorisation of Insulin Human Rechon for the treatment of patients with diabetes who need insulin to keep their blood glucose (sugar) level controlled.

The company withdrew the application on 18 March 2025.

What is Insulin Human Rechon and what was it intended to be used for?

Insulin Human Rechon was developed as a medicine for the treatment of patients with diabetes who need insulin to keep their blood glucose level controlled.

Insulin Human Rechon contains the active substance insulin human and was to be given by injection under the skin.

Insulin Human Rechon was developed as a 'biosimilar' medicine. This means that it was intended to be highly similar to another biological medicine already authorised in the EU (the 'reference medicine'). The reference medicine for Insulin Human Rechon is Humulin Regular. For more information on biosimilar medicines, see here.

How does Insulin Human Rechon work?

Diabetes is a disease in which the body does not produce enough insulin to control the level of glucose in the blood or when the body is unable to use insulin effectively. The active substance in Insulin Human Rechon, insulin human, is a replacement insulin designed to work in the same way as the insulin made by the body, helping glucose enter the cells from the blood. This was expected to control the level of blood glucose and reduce the symptoms and complications of diabetes.

What did the company present to support its application?

The company presented results from laboratory studies that investigated whether the active substance in Insulin Human Rechon is highly similar to that in Humulin Regular in terms of structure, purity and biological activity.

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

The company also presented results from two clinical studies. The first involved healthy volunteers in a controlled study setting and looked at whether Insulin Human Rechon behaves in the body in the same way as Humulin Regular. The second study involved patients with diabetes and compared the long-term safety of Insulin Human Rechon with that of Humulin Regular when used in the real-life setting.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and prepared questions for the company. After the Agency had assessed the company's responses to the last round of questions, there were still some unresolved issues.

What did the Agency recommend at that time?

Based on the review of the data and the company's response to the Agency's questions, at the time of the withdrawal, the Agency had some concerns and its provisional opinion was that Insulin Human Rechon could not have been authorised for the treatment of patients with diabetes who need insulin to keep blood glucose level controlled.

The Agency's concerns related to how the study in healthy volunteers had been carried out, which meant that it was not possible to rule out that insulin produced by the volunteers' own bodies may have affected the results. As a result, no conclusion could be drawn on whether Insulin Human Rechon behaves in the body in the same way as the reference medicine Humulin Regular.

Therefore, at the time of the withdrawal, the Agency's opinion was that the company had not provided enough data to demonstrate that Insulin Human Rechon is a biosimilar of Humulin Regular.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of the application, the company stated that the withdrawal is based on business reasons.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no ongoing clinical trials with Insulin Human Rechon.