14 November 2025
EMA/356296/2025
EMEA/H/C/006720

Withdrawal of application for the marketing authorisation of Insulin Aspart Injection (insulin aspart)

Masuu Pharma Europe Limited withdrew its application for a marketing authorisation of Insulin Aspart Injection for the treatment of diabetes.

The company withdrew the application on 17 October 2025.

What is Insulin Aspart Injection and what was it intended to be used for?

Insulin Aspart Injection was developed as a medicine for the treatment of diabetes in adults and children aged 1 year and above.

It contains the active substance insulin aspart and was to be available as a solution for injection in a vial, cartridge and prefilled pen.

Insulin Aspart Injection 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 Aspart Injection is NovoRapid. For more information on biosimilar medicines, see here.

How does Insulin Aspart Injection work?

In diabetes, patients have high levels of blood glucose (sugar) either because the body does not produce enough insulin or the body is unable to use insulin effectively.

The active substance in Insulin Aspart Injection, insulin aspart, is a form of insulin that is absorbed more quickly by the body than regular insulin and can therefore act faster. It was expected to help control blood glucose levels, thereby alleviating symptoms of diabetes and reducing the risk of complications.

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

What did the company present to support its application?

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

The company also provided the results of two clinical studies. The first involved healthy volunteers and looked at whether the active substance of Insulin Aspart Injection behaves in the body in the same way as the active substance of NovoRapid.

The second study involved 320 adults with type 2 diabetes whose blood glucose levels were not sufficiently controlled with a mixture of fast and intermediate-acting insulin. The study compared the effect of Insulin Aspart Injection with that of NovoRapid (each given together with a long-acting insulin) on HbA1c after 24 weeks; HbA1c is a measurement that gives an indication of how well blood glucose levels are controlled over time.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn while the European Medicines Agency was still evaluating the initial information from the company.

What did the Agency recommend at that time?

As the Agency was still evaluating the initial information from the company, it had not yet made any recommendations.

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 its manufacturing and testing site is undergoing modifications and will not be ready for pre-approval inspection.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no ongoing clinical trials with Insulin Aspart Injection.