10 November 2016
EMA/CHMP/702450/2016
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Fiasp

## insulin aspart

On 10 November 2016 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Fiasp, intended for the treatment of diabetes in adults. The applicant for this medicinal product is Novo Nordisk A/S.

Fiasp will be available as a solution for injection (100 units/ml). The active substance of Fiasp is insulin aspart, a fast-acting insulin analogue (ATC code: A10AB05) which is absorbed more rapidly by the body and can therefore act faster than human insulin. The replacement insulin acts in the same way as naturally produced insulin; it works by facilitating uptake of glucose into skeletal muscle and fat tissue, and by inhibiting glucose output from the liver.

The benefits with Fiasp are its ability to control blood glucose. The most common side effect is hypoglycemia.

The full indication is: "Treatment of diabetes mellitus in adults."

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

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