EDA Assessment Report for Biological Medicinal Product

(Scientific Discussion)

fiasp

Date: November 2024

Unit: Technical Assessment Unit

Assessment report
Fiasp
Administrative information:

Trade name of the medicinal product:	Fiasp
INN (or common name) of the active substance(s):	Insulin aspart 100 U/ml
Manufacturer of the finished product	Novo Nordisk A/S, Novo Allé, 2880 Bagsvaerd - Denmark.
Marketing Authorization holder	Novo Nordisk A/S, Novo Allé, DK-2880 Bagsvaerd - Denmark
Applied Indication(s):	Fiasp is a mealtime insulin with a fast-acting blood sugar lowering effect. Fiasp is a solution for injection containing insulin aspart and is used to treat diabetes mellitus in adults, adolescents and children aged 1 year and above. Diabetes is a disease where your body does not produce enough insulin to control the level of blood sugar. Treatment with Fiasp helps to prevent complications from your diabetes.
Pharmaceutical form(s) and strength(s):	- Solution for injection in prefilled Pen -Strength: 100 U/ml
Route of administration	Subcutaneous injection,
Approved pack	Carton box containing 1 or 5 pre-filled pens (without needles) made of polypropylene, polyoxymethylene, polycarbonate and acrylonitrile butadiene styrene, each of 3 mL solution with insert leaflet. Each pre-filled pen contains a cartridge (colorless glass type 1) with a rubber plunger (grey chlorobutyl) and a laminate rubber stopper (bromobutyl /polyisoprene) inserted in an aluminium cap

List of abbreviations:

CSII	Continuous subcutaneous insulin infusion
FP	finished product

Dossier initial submission and evaluation process:

- The product was submitted for registration via Normal Track
- The dossier was initially received by the registration administration units on 10.11.2021 after providing all the required documents according to Preliminary checklist.

1. **'General introduction about the product including brief description of the AI, its mode of action and indications**:

-The active substance of Fiasp has been developed Novo Nordisk A/S, Hallas Alle, 4400 Kalundborg - Denmark & Novo Nordisk A/S, Novo Allé, 2880 Bagsvaerd – Denmark.
-The finished product (FP) is a clear colorless or almost colorless liquid free from turbidity and essentially free from particulate matter.
- all excipients are also components of the approved NovoRapid® formulation. The composition of the faster-acting insulin aspart drug product is chosen to optimize the chemical and physical stability as well as the clinical properties of the drug product.
- The product is available in 3 ml cartridge is made of clear colourless glass with high hydrolytic resistance (type I glass). The cartridge meets the requirements for type I glass defined in Ph. Eur., USP and JP
- Structural formula Insulin aspart is an analogue of human insulin where the amino acid proline has been replaced with aspartic acid in position B28. The lines represent the inter-chain disulphide bonds connecting the Aand B-chain, and the intra-chain disulphide bond in the A-chain. Insulin aspart is produced using recombinant DNA technology in yeast (Saccharomyces cerevisiae).
-Fiasp is used to treat diabetes mellitus in adults, adolescents and children aged 1 year and above. Diabetes is a disease where your body does not produce enough insulin to control the level of blood sugar. Treatment with Fiasp helps to prevent complications from your diabetes.

2. **Quality aspects:**

- **Manufacturer(s):**

-The active substance is performed at
1-Novo Nordisk A/S, Hallas Alle, 4400 Kalundborg - Denmark.
2-Novo Nordisk A/S, Novo Allé, 2880 Bagsvaerd – Denmark.

-The drug product is performed at Novo Nordisk A/S, Novo Allé, 2880 Bagsvaerd – Denmark. & Novo Nordisk Pharmaceutical Industries, LP3612 Powhatan Road Clayton, North Carolina 27527 USA

-Batch release site is performed at Novo Nordisk A/S, Novo Allé, 2880 Bagsvaerd – Denmark & Novo Nordisk Pharmaceutical Industries, LP3612 Powhatan Road Clayton, North Carolina 27527 USA

- **Stability**

Drug substance:

Approved Shelf Life: 60 months

Approved storage Conditions: at temperature (-20°C±5°C)

Drug product:

Approved Shelf Life: 30 Months

Approved Storage Conditions:

Before opening:

Store in a refrigerator (2°C–8°C).
Do not freeze.
Keep away from the freezing element.
Keep the cap on the pen in order to protect from light.

After opening or carried as a spare:

The medicinal product may be Stored for maximum of 4 weeks.
Do not store above 30°C.
Can be stored in the refrigerator (2°C–8°C).
Do not freeze.
Keep the cap on the pen in order to protect from light

3. Non-clinical aspect and clinical aspect

-The early absorption of insulin aspart was significantly increased for faster aspart compared to NovoRapid® /NovoLog® in pigs and was accompanied by an earlier decline in plasma glucose. The vast experience with the active ingredient insulin aspart as NovoRapid® /NovoLog® within diabetes management, the literature safety review on the added excipients, the local tolerance studies and the safety evaluation of the impurity profile of faster aspart all support the safe use of faster aspart for chronic treatment of diabetes mellitus.

-In conclusion the overall benefit/risk of Fiasp is favorable in the treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above

- **General Conclusion and Recommendations if any:**
  Based on the review of CTD modules and other supplementary documents, the product is approved.
  For more information, please visit EMA published assessment report link:
  https://www.ema.europa.eu/en/documents/overview/fiasp-epar-medicine-overview_en.pdf