

Medicine Shortage Communication

<Date>

Fiasp 100 units/mL PumpCart solution for injection in cartridge (insulin aspart) and NovoRapid PumpCart 100 units/mL solution for injection in cartridge (insulin aspart): Supply shortage and cessation of marketing for Fiasp Pumpcart

Dear Healthcare Professional,

Novo Nordisk A/S [affiliate to include country specific information to reflect global or local company name] is notifying healthcare professionals about potential or ongoing shortages of Fiasp PumpCart and NovoRapid PumpCart

Overview of situation

- **Current manufacturing capacity cannot meet the demand for Fiasp 100 U/mL PumpCart solution for injection in cartridge and NovoRapid PumpCart 100 U/mL solution for injection in cartridge. This has led, or may lead to intermittent shortages throughout 2025.**
- **The shortages are not related to a quality defect or an efficacy or safety issue.**
- **In addition, due to commercial reasons, marketing of Fiasp PumpCart will cease by the end of 2026 at the latest in all EU/EEA countries where the product is currently marketed.**

Mitigation measures

In order to manage the shortage, Novo Nordisk is engaging with the European Medicines Agency and the [National Competent Authority] on mitigation measures.

The product shortage could result in patients missing the required doses, which may lead to serious clinical consequences, specifically hyperglycaemia that may eventually progress to diabetic ketoacidosis.

Healthcare professionals (HCPs) should consider the following mitigation measures:

- No new patients should be started on Fiasp PumpCart or NovoRapid PumpCart throughout 2025.
- In case Fiasp PumpCart or NovoRapid PumpCart is unavailable, healthcare professionals should switch existing patients to an alternative fast-acting insulin therapy (such as Fiasp, NovoRapid or its insulin aspart biosimilars, fast-acting insulin lispro or its biosimilars, insulin glulisine or its biosimilars, insulin lispro or its biosimilars), based on existing guidance and clinical judgment. In case a switch from the current therapy is needed, healthcare professionals should ensure that all patients are counselled on any changes and provided with adequate training, if needed.

Background information

- Fiasp PumpCart¹ and NovoRapid PumpCart² are insulin analogues indicated for the treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above [affiliate to include country specific **indication** information]. [affiliate to include country specific **presentation** information].

Company contact point

Further information can be obtained by contacting [<local Novo Nordisk affiliate contact details to be added by affiliate>](#)

Yours Sincerely,

Medical Director

Annexes

References:

1. Fiasp Summary of Product Characteristics. Aug 2021.
2. NovoRapid Summary of Product Characteristics. March 2023.

Communication Plan for Medicine Shortage Communication

MSC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Fiasp 100 units/mL PumpCart solution for injection in cartridge (insulin aspart) and NovoRapid PumpCart 100 units/mL solution for injection in cartridge (insulin aspart).
Marketing authorisation holder(s)	Novo Nordisk A/S
Purpose of the communication	Inform Healthcare professionals on potential or ongoing shortages of Fiasp PumCart, NovoRapid PumpCart and marketing cessation of Fiasp PumpCart and measures to take.
MSC recipients	Target group for this letter is specialists that treat patients with diabetes (e.g. endocrinologists, diabetologists, specialists in internal medicine, general practitioners /family physicians, pharmacists, diabetes nurses) in all EU/EEA countries in which the medicinal products are marketed. The target group can be further defined at national level, in agreement with the respective national competent authority.
Member States where the MSC will be distributed	In agreement with the national competent authorities.
Timetable <i>[Delete steps which are not applicable]</i>	
MSC and communication plan (in English) agreed by SPOC WP	22 April 2025
MSC and communication plan (in English) agreed by MSSG	25 April 2025
Submission of translated MSCs to the national competent authorities for review	2 May 2025
Agreement of translations by national competent authorities	by 5 May 2025
Dissemination of MSC	by 8 May 2025