DHPC LETTER FOR MARCH 2024

Date: 20 March 2024

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Fiasp® FlexTouch® (fast-acting insulin aspart) 100 units/ml solution for injection 3ml pre-filled pen: Supply Shortage in the UK

Dear Healthcare Professional,

Novo Nordisk UK in agreement with the Medicines and Healthcare Products Regulatory Agency (MHRA) and the Department of Health and Social Care (DHSC) would like to inform you of the following:

A supply shortage for Fiasp FlexTouch 100 U/ml solution for injection

Summary:

- Fiasp FlexTouch is indicated for the treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above
- Novo Nordisk is currently experiencing a shortage of Fiasp FlexTouch 100 U/ml. The shortage is expected to continue until at least January 2025
- Rationale for shortage: Novo Nordisk is serving more patients than ever before and has seen higher demand than we expected for many of our products. As a result, we are experiencing limitations in our manufacturing capacity. Other presentations of Fiasp are available and unaffected. This shortage is not due to any safety or quality related concerns.
- We are taking steps to increase the number of medicines produced at our manufacturing sites to address the high demand we are seeing.
- It is important to ensure that patients currently using Fiasp FlexTouch 100 U/ml are supported to change to an alternative treatment as soon as possible. Please refer to the advice provided in the Medicines Shortage Notification (MSN) (MSN/2024/027- available on Medicine Supply Tool).

Background on the safety concern:

Please refer to the Summary of Product Characteristics (SmPC) for the detailed therapeutic indication
Fiasp FlexTouch SmPC: https://www.medicines.org.uk/emc/product/2447

A Medicines Shortage Notification (MSN/2024/027) was issued by the DHSC on 4th March 2024. This is available on Medicine Supply Tool within the Specialist Pharmacy Service website. You may need to register to access the Medicine Supply Tool (www.sps.nhs.uk/wp-login.php).

Advice for healthcare professionals:
You are urged to notify patients who are currently using the Fiasp FlexTouch 100 U/ml of the shortage and to support them to change to an alternative treatment as per advice provided in the MSN/2024/027.

Delayed awareness of out-of-stock situation, delayed action to support patients to change to an alternative treatment and incorrect prescribing, dispensing and administration of the required dose could result in patients missing the required doses, which may have clinical consequences, such as hyperglycaemia and eventually progression to diabetic ketoacidosis.

- Recommendation is to switch to an alternative insulin injection device other than Fiasp FlexTouch. Where this is not possible due to a patient's dexterity or ability to use the new device, seek advice from specialist diabetes teams on the use of an alternative insulin.

- If a switch to Fiasp Penfill 100 U/ml is deemed clinically appropriate, ensure the patient is also supplied with a compatible Novo Nordisk insulin delivery system and appropriate needles. If applicable, refer to the relevant device user guides and other product information such as, the Summary of Product Characteristics (SmPC) for the detailed therapeutic indication for Fiasp Penfill SmPC: https://www.medicines.org.uk/emc/product/8108

- Ensure all patients initiated on a new device are counselled on the change and provided with training on their use and the potential need for closer monitoring of blood glucose levels.

- If a switch to an alternative fast-acting basal insulin is deemed clinically appropriate, this should be done only after careful consultation with a physician and under strict medical supervision. Please note, Fiasp and NovoRapid are not interchangeable due to differences in bioavailability where Fiasp has a quicker onset of action and shorter duration.

- No new patients should be initiated on Fiasp FlexTouch 100 U/ml pre-filled pens during this shortage.

- Remind your colleagues of these actions, particularly if they are known to use/prescribe Fiasp FlexTouch.

Please ensure that all relevant staff are made aware of the contents of this letter and that the information is communicated to the affected patients.

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life- threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼.

Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card scheme. You can report via:

- The Yellow Card website - https://yellowcard.mhra.gov.uk/
- The free Yellow Card app available from the Apple App Store or Google Play Store
- Some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

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The non-identical nature of biological medicines and vaccines means it is very important that safety surveillance is carried out on a brand/product-specific basis. When reporting a suspected ADR to a biological medicine (such as blood products, antibodies and advanced therapies [such as gene and tissue therapy]) or vaccine, please ensure that you provide the brand name (or product license number and manufacturer), and the specific batch-number. Additionally, when providing patients with details of the vaccine or biological medicine administered, it is good practice to give them details of the brand and batch number. This will allow patients and carers to more accurately report suspected ADRs to the Yellow Card scheme.

Company contact point

If you have any questions about this letter or require more information, please contact Novo Nordisk Customer Care Centre on 0800 023 2573.

I understand the uncertainty and concern this shortage may cause people living with diabetes. This is not something we are taking lightly, and we are working hard to solve these challenges.
Yours sincerely,

Dr. Avideh Nazeri
Vice President
Clinical Development, Medical and Regulatory Affairs (CMR), Novo Nordisk UK

Avideh Nazeri

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