



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy / Wholesaler Level

Date: 21 July 2022

EL (22)A/33

Our Ref: MDR 200-05/22

Dear Healthcare Professional,

Novo Nordisk Limited

NovoRapid® FlexTouch® 100 units/ml solution for injection in pre-filled pen (insulin aspart)

PL GB 04668/0369
(not implemented on packs yet)

EU/1/99/119/020

Batch No	Expiry Date	Pack Size	First Distributed
MZF0M05	31-10-2023	5 cartridges	22-Mar-2022
MZF1H04	30-04-2024	5 cartridges	13-May-2022

Active Pharmaceutical Ingredient: insulin aspart

Saxenda® FlexTouch® (liraglutide) 6mg/ml Solution for injection in pre-filled pen

PL GB 04668/0409

EU/1/15/992/003

Batch No	Expiry Date	Pack Size	First Distributed
LZFW572	30-11-2023	5 Pre-filled pens	23-Feb-2022
LZF0H19	31-01-2024	3 Pre-filled pens	06-Jun-2022
LZF0D36	29-02-2024	3 Pre-filled pens	08-Mar-2022
LZF0D41	31-12-2023	5 Pre-filled pens	23-Jun-2022
LZFW142	31-07-2023	3 Pre-filled pens	02-Sep-2021
LZFW571	30-11-2023	5 Pre-filled pens	16-Nov-2021
LZFY408	30-11-2023	5 Pre-filled pens	16-Dec-2021
LZFY613	31-12-2023	5 Pre-filled pens	16-Dec-2021
MZF0V95	30-04-2024	3 Pre-filled pens	28-Mar-2022
MZF1B51	30-04-2024	5 Pre-filled pens	17-Mar-2022

Active Pharmaceutical Ingredient: liraglutide



Brief description of the problem

Novo Nordisk Limited would like to notify you of a defect that affects specific batches of NovoRapid FlexTouch prefilled pen device and batches of Saxenda FlexTouch prefilled pen device in the UK.

The defect results in a non-functioning device where it is not possible to set a dose because the dose selector will spin freely, as such, click sounds will not be heard. Since a dose cannot be selected, the patient cannot inject a dose. A very small number of pens are affected – the average number of affected products is 2-3 pens per million pens. Based on the critical need for the products, they are not being recalled.

Advice for healthcare professionals

This information relates to both NovoRapid and Saxenda FlexTouch pens. If the pen is faulty, it will not be possible to set a dose because the dose selector will spin freely, as such, click sounds will not be heard. Since a dose cannot be selected, the patient cannot inject a dose therefore the fault will be noticeable to the patient.

- If a patient returns a faulty pen from these batches to their pharmacy or other healthcare professional, Novo Nordisk request that the healthcare professional follows the usual safety and complaints process whereby they provide the patient with a replacement pen.
 - The healthcare professional should then contact Novo Nordisk Customer Care to report it and obtain a pre-paid jiffy bag in order to return the faulty pen to Novo Nordisk who will credit the healthcare professional via their Alliance Healthcare (wholesaler) account.
- **Patients are advised to always carry a spare pen to avoid any doses being missed.** The pens with the affected defect are not being recalled. Patients can continue to use pens from these batches if not affected by the defect.

Advice for patients

Patients can continue to use pens from these batches; this is because only a small number of pens are affected by the defect. The defect means that some pens will not work. The defect results in a non-functioning device where it is not possible to set a dose because the dose selector will spin freely, as such, click sounds will not be heard. Since a dose cannot be selected, the patient cannot inject a dose.

If patients receive a defective pen, they should contact their healthcare professional to obtain a new supply. Patients are advised to always carry a spare pen to avoid any doses being missed.

- **NovoRapid:** If you miss a dose of this medicine, your blood sugar may become high. You should use a replacement pen to administer a dose as soon as possible. In the meantime, monitor your blood sugar levels more often than usual. Contact your healthcare professional if you have any concerns.
- **Saxenda:** If you miss a dose due to a defective pen you should obtain a replacement. If there is more than 12 hours until your next scheduled dose, then take it soon as possible. If there is less than 12 hours until your next usual dose, do not take the missed dose and resume your once-daily regimen with the next scheduled dose. An extra dose or increase in dose should not be taken to make up for the missed dose. Contact your healthcare professional if you have any concerns.



Medicines & Healthcare products
Regulatory Agency

Further Information

For medical information and stock control queries please contact: **Customer Care contact details**
+44 (0)800 023 2573 or CustomerCare@novonordisk.com

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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