Date: 27-Feb-2023

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Ozempic® solution for injection in pre-filled pen (Semaglutide): supply shortage in the UK

Dear Healthcare Professional,

Summary: Novo Nordisk is currently experiencing supply Shortage with Ozempic® Solution for injection in pre-filled pen (Semaglutide) in the UK.

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:

- Increased demand for Ozempic has led to intermittent shortages which are expected to continue throughout 2023. While supply will continue to increase, it is uncertain when it will be sufficient to fully meet current demand.

- The shortage is not a consequence of any safety or quality related concern with Ozempic.

- During this shortage period, as per DHSC recommendation no new patients should be initiated on Ozempic.

- Delayed awareness of the out-of-stock situation may result in patients missing the required doses, which may have clinical consequences such as hyperglycaemia.

- You are urged to ensure that patients using Ozempic are made aware of this issue and that patients at risk of running out of Ozempic are safely switched to another glucagon-like peptide-1 receptor agonist or other suitable alternatives based on your clinical judgment.

- Ozempic is only indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise, as monotherapy when metformin is considered inappropriate due to intolerance or contraindications, or in addition to other medicinal products for the treatment of diabetes. Any other use, including for weight management, represents off-label use and currently places the availability of Ozempic for the indicated population at risk.

- A Medicines Shortage Notification (MSN) (MSN/2022/080) has been issued by the Department of Health and Social Care (DHSC) for Ozempic.

- Novo Nordisk is also aware of an MSN which has been issued for another injectable GLP1-RA.

- Alternative oral and parenteral GLP-1 receptor agonists remain available. Always refer to individual medicines' Summary of Product Characteristics (SmPCs).

- For patients who are required to be switched to alternative GLP-1 receptor agonist products, this should only be done after careful consultation with a physician and require strict medical supervision.

Further guidance is available via the MSN (MSN/2022/080) delivered by the DHSC. An updated version is available on the Medicines Supply Tool within the Specialist Pharmacy Service website.

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

Call for reporting
Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website https://yellowcard.mhra.gov.uk/, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effects can also be reported by calling 0800 731 6789 for free.
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.

Suspected adverse reactions can also be reported to Novo Nordisk's customer care centre on 0800 023 2573.

Ozempic® ▼ is subject to additional monitoring. This will allow quick identification of new safety information. Please report ANY suspected adverse drug reactions (ADRs) to new drugs and vaccines identified by the black triangle ▼ to the MHRA through the Yellow Card Scheme.

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 licence 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 about Ozempic®, 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,

Avideh Nazeri

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