

IMPORTANT INFORMATION - SHORTAGE NOTIFICATION

**Ozempic® (semaglutide) 0.5 mg solution for injection in pre-filled pen
(EU/1/17/1251/003)**

**Ozempic® (semaglutide) 1 mg solution for injection in pre-filled pen
(EU/1/17/1251/005)**

08 September 2023

Dear Healthcare Professional,

Novo Nordisk Limited, Ireland in agreement with the Health Products Regulatory Authority (HPRA) would like to inform you of the following:

Shortage Summary

- A shortage of Ozempic® (semaglutide) 0.5 mg solution for injection in pre-filled pen (EU/1/17/1251/003) **and** Ozempic® (semaglutide) 1 mg solution for injection in pre-filled pen (EU/1/17/1251/005) is expected as follows:
 1. **Ozempic® 0.5 mg: Early October 2023**
 2. **Ozempic® 1.0 mg: Mid-September 2023**
- A return to stock for both products is expected **week commencing 11 Oct 2023**.
- **Novo Nordisk recommends that no new patients are initiated on Ozempic® during the shortage period.**
- Updated information on the availability of Ozempic® will be available on the shortages section of the HPRA website (www.hpra.ie).
- The shortage is due to Ozempic® production delays and general demand pressure in the Glucagon-Like Peptide-1 Receptor Agonist (GLP-1 RA) class and is not a consequence of any safety or quality related issues.
- The out-of-stock situation could result in patients missing required doses, which may have clinical consequences such as hyperglycaemia.
- **Healthcare professionals (HCPs) are urged to ensure that patients using Ozempic® are made aware of this shortage and that patients at risk of running out of Ozempic® are safely switched to another GLP-1 RA or other suitable alternative, based on your clinical judgement and market availability. Novo Nordisk requests that patients are not switched from Ozempic® to Victoza® (liraglutide) as increased demand may impact the supply of Victoza®.**
- **HCPs are requested to remind their team of these actions, particularly if they are known to be Ozempic® prescribers. We would appreciate if you could please ensure that all relevant members of your team are made aware of this important information.**
- Ozempic® pens are single dose pens, which deliver the specified dose. Novo Nordisk do not recommend that patients use an alternative Ozempic® dose pen to try and achieve their prescribed dose. This practice is not supported by the license for Ozempic®. Additionally, transfer of patients to alternative strength Ozempic® will place challenges on the supply of these medicines.

Ozempic® indication

Ozempic® is 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
- in addition to other medicinal products for the treatment of diabetes¹.

Any other use, including for weight management, represents off-label use and currently places the availability of Ozempic® for the indicated population at risk. Please refer to *Section 4.1 Therapeutic indications* of the Ozempic® Summary of Product Characteristics (SmPC) available on www.medicines.ie for additional information.

Ozempic® supply challenges in Ireland

Notwithstanding the shortage detailed above, increased demand for Ozempic® has led to supply challenges over the last 12 months, which are expected to continue throughout 2023. While supply will continue to increase, it is uncertain when it will be sufficient to meet full demand.

Allocations are in place and pharmacies should contact their wholesaler directly regarding allocation related enquiries.

Call for reporting

Adverse events including medication errors relating to Ozempic® should be reported to Novo Nordisk Limited, Ireland on 01 8629700 or complaintireland@novonordisk.com, or to the HPRA at www.hpra.ie.

Company contact point

Further information can be obtained by contacting Novo Nordisk Limited, Ireland on 01 8629700 or infoireland@novonordisk.com.

Novo Nordisk recognises the uncertainty and concern this shortage may cause patients being treated with Ozempic®. We apologise for the disruption and inconvenience this may cause. This is something we take seriously, and we are working hard to resolve these challenges.

Yours sincerely,



Dr. Donna Sexton
Clinical, Medical and Regulatory Director
Novo Nordisk Limited, Ireland

Reference:

1. Novo Nordisk. Ozempic® (semaglutide) Summary of Product Characteristics (SmPC).
Revision date 03/2023, www.medicines.ie

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September 2023, IE23OZM00023

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