

## IMPORTANT INFORMATION

### SUPPLY UPDATE

#### **Ozempic® (semaglutide) solution for injection in pre-filled pen (EU/1/17/1251/002, 003, 005)**

24-Mar-2023

Dear Healthcare Professional,

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

#### **Summary:**

- Increased demand for Ozempic® has led to 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.
- Delayed awareness of out-of-stock situations 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 (GLP-1) receptor agonist, or other suitable alternatives based on your clinical judgement.
- Ozempic® is only indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise. Any other use, including for weight management, represents off-label use and currently places the availability of Ozempic® for the indicated population at risk.

#### **Background**

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 diabetes<sup>1</sup>.

Any other use, including for weight management, represents off-label use and currently places the availability of Ozempic® for the indicated population at risk.

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Higher than expected demand has resulted in intermittent shortages of Ozempic®. The shortages are expected to continue throughout 2023. While supply will continue to increase, it is uncertain when it will be sufficient to meet full demand. The supply shortage is not related to a quality defect of the product or a safety issue.

We kindly request your support to ensure that patients using Ozempic® 0.25 mg, 0.5 mg and 1 mg solution for injection in pre-filled pen are made aware of this issue and that patients at risk of running out of Ozempic® are switched to another GLP-1 receptor agonist or other suitable alternatives as per market availability.

### **Ozempic® supply in Ireland**

To ensure long-term continuity of stable supply of Ozempic® to the Irish market, Novo Nordisk are releasing a proportional level of Ozempic® stock to secondary wholesalers on a month-by-month basis. Secondary wholesalers have also implemented proportional allocations at pharmacy level to ensure continuity of supply. As a result of the above actions, supply may not meet demand at pharmacy level and will result in intermittent delays in receiving stock of Ozempic® by pharmacies.

### **Call for reporting**


Adverse events including medication errors relating to Ozempic® FlexTouch® or alternative Novo Nordisk products should be reported to Novo Nordisk Medical Department at [complaintireland@novonordisk.com](mailto:complaintireland@novonordisk.com) or Tel: 01 8629700 or to the Health Products Regulatory Authority at [www.hpra.ie](http://www.hpra.ie).

### **Company contact point**

Further information can be obtained by contacting Novo Nordisk Limited, Ireland on 01 8629700 or [infoireland@novonordisk.com](mailto:infoireland@novonordisk.com).

Novo Nordisk Limited, Ireland will continue to provide updates on this supply situation to the HPRA and Health Service Executive as new information becomes available. Novo Nordisk is working diligently to manage supply of Ozempic® in order to minimise the impact of this increase in demand. We sincerely apologise for this unfortunate situation and any inconvenience it may cause.

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 09/2022. [www.medicines.ie](http://www.medicines.ie)