



10, October 2022

Direct Healthcare Professional Communication (DHPC)

## **Ozempic®(semaglutide) solution for injection in pre-filled pen: supply shortage**

Dear Healthcare Professional,

Novo Nordisk A/S, Novo Allé DK-2880 Bagsværd, Denmark, in agreement with the European Medicines Agency and the Medicine Authority of Malta would like to inform you of the following:

### **Summary:**

- Increased demand for Ozempic® has led to intermittent shortages which are expected to continue into 2023
- 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 judgement

### **Background**

Ozempic® is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise <sup>(1)</sup>

- as monotherapy when metformin is considered inappropriate due to intolerance or contraindications;
- in addition to other medicinal products for the treatment of diabetes.

Higher than expected demand has resulted in a shortage of Ozempic®. The shortages will be intermittent and continue into 2023. The supply shortage is not related to a quality defect of the product or a safety issue.

#### **Novo Nordisk S.p.A.**

Società con socio unico  
Direzione e Coordinamento  
Novo Nordisk A/S (Danimarca)  
Capitale Sociale € 516.500,00 i.v.

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We kindly request your support to ensure that patients using Ozempic® FlexTouch® [0.25 mg, 0.5 mg and 1 mg] are made aware of this issue and that patients at risk of running out of Ozempic® FlexTouch® [0.25 mg, 0.5 mg and 1 mg] are switched to another glucagon-like peptide-1 receptor agonist or other suitable alternatives as per market availability.

### **Call for reporting**

Adverse events including medication errors relating to Ozempic® FlexTouch® or alternative Novo Nordisk products should be reported to Novo Nordisk SpA [via Elio Vittorini 129, 00144 Rome, Italy - Web site <https://www.novonordisk.it/>] or to local authority through ADR Reporting Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal).

### **Company contact point**

Further information can be obtained by contacting Charles de Giorgio Ltd. Triq il-Kan. Karmenu Pirotta, B'Kara, BKR 1114 Malta. Telephone: (+356) 2560 0500 Fax: (+356) 2560 0200 Website: <https://charlesdegiorgio.com/>

Novo Nordisk AS, Novo Allé DK-2880 Bagsværd, Denmark, will continue to provide updates on this supply situation to your local health authority as new information becomes available. At Novo Nordisk we are working around the clock to maximise existing production while investing heavily in new capacity to remedy these shortages. We sincerely apologise for this unfortunate situation and any inconvenience it may cause.

Yours Sincerely

Marcella Marcellini  
Regulatory and Safety Manager

On behalf of

Amale Chalfoun, MD  
Senior Clinical, Medical and Regulatory Director  
CMR Department-Italy

#### References:

1. Novo Nordisk. Ozempic® (semaglutide) Summary of Product Characteristics. 2022

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