# Victoza® 6 mg/mL solution for injection in pre-filled pen (liraglutide): Risk of supply shortage due to marketing cessation (discontinuation)

Dear Health Professional,

Novo Nordisk S.p.A., legal representative in Italy of Novo Nordisk A/S, in agreement with the European Medicines Agency (EMA) and the Italian Medicines Agency (AIFA), would like to inform you about the cessation of marketing (discontinuation) of Victoza® (liraglutide) in all EU/EEA countries. This discontinuation could lead to intermittent short-term shortages in some countries.

#### Overview of situation:

- Novo Nordisk will discontinue Victoza® across the EU/EEA by the end of 2026.
- Due to the marketing cessation, there may be a risk of short-term intermittent shortages in some countries until the product is no longer marketed.
- Timelines for the discontinuation vary from country to country but will be completed in all EU member states by December 2026.
- The discontinuation in Italy will occur on June 30, 2026.
- The cessation of marketing is for commercial reasons and is not a consequence of any safety or quality concerns.

### Mitigation measures

Novo Nordisk is engaging with the European Medicines Agency and AIFA on mitigation measures.

Regulatory authorities, physicians, healthcare providers and patient organisations are being informed to help ensure patients transition safely to alternative options for continuity of care.

Patients need to be switched to an alternative treatment in time to avoid the risk of missing doses, which may lead to serious clinical consequences.

## Healthcare professionals (HCPs) should consider the following mitigation measures:

- No new patients should be started on Victoza®.
- Healthcare professionals should switch all patients who are currently on Victoza® to alternative GLP-1 analogues or other alternative medication based on existing guidance and clinical judgement.

- Healthcare professionals are requested to follow the relevant Summary of Product Characteristics (SmPCs) of the alternative products for dosing recommendations while switching patients to alternative products.
- Healthcare professionals are requested to provide clear instructions of usage to the patient, if switched to alternative GLP-1 analogue or other alternative.
- Close glucose monitoring is recommended during the switch to another type or brand
  of alternative GLP-1 analogue or other alternative and patients should be fully informed
  about any relevant changes.

#### **Basic Information**

Victoza ® is indicated for the treatment of adults, adolescents and children aged 10 years and above 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.

Victoza ® (liraglutide) is authorised in the formulation 6 mg/mL solution for injection in prefilled pen - subcutaneous use - 3 ml - 2 pre-filled pens - AIC n. 039365010/E

For up-to-date information on the availability of Victoza® and alternatives in a particular EU/EEA country, please consult the National Competent Authority.

For any update on the state of shortage, please refer to the List of Medicines in Shortage, which is periodically updated and published at the following link:

https://www.aifa.gov.it/documents/20142/2171819/6\_Elenco\_farmaci\_carenti.ods

# **Adverse Event Reporting**

Adverse events including medication errors related to Victoza® (liraglutide) should be reported to Novo Nordisk S.p.A. and the Italian Medicines Agency via the following link <a href="https://www.aifa.gov.it/web/guest/content/segnalazioni-reazioni-avverse">https://www.aifa.gov.it/web/guest/content/segnalazioni-reazioni-avverse</a>.

AIFA takes this opportunity to remind all healthcare professionals of the importance of reporting suspected adverse drug reactions, as an indispensable tool to confirm a favorable benefit-risk ratio in real conditions of use. Reports of Suspected Adverse Drug Reactions must be sent to the Pharmacovigilance Responsible of the Operator's Facility. This Information Note is also published on the AIFA website (<a href="www.agenziafarmaco.it">www.agenziafarmaco.it</a>), whose regular consultation is recommended for the best professional and service information to the citizen.

# Company contact point - Novo Nordisk SpA

Further information on drug shortages and medical information can be obtained by contacting Novo Nordisk S.p.A, Viale Giorgio Ribotta 35-37 00144 Rome, Italy- +39 06 500881- Website <a href="https://www.novonordisk.it/">https://www.novonordisk.it/</a>