

Direct Healthcare Professional Communication

Ozempic (semaglutide) and Victoza (liraglutide): Supply shortage

Dear Healthcare Professional,

Novo Nordisk [affiliate to include country specific information to reflect global or local company name] in agreement with the European Medicines Agency and the <National Competent Authority> would like to inform you of the following:

Summary

- Increased overall demand for Ozempic and Victoza injectable glucagon-like peptide-1 receptor agonists (GLP-1 RAs) coupled with capacity constraints at some of our manufacturing sites have led to shortages, including out-of-stock situations. In addition, to facilitate increasing supply of Ozempic, Novo Nordisk decided to temporarily reduce the supply of Victoza. The shortage situation for Ozempic and Victoza will deteriorate in Q4 2023.
- For Ozempic, intermittent shortages are expected throughout 2024. For Victoza, shortages are expected at least until Q2 2024. The supply shortage is not related to a quality defect of the products or a safety issue.
- No new patients should be started on Victoza until at least Q2 2024 when supply is expected to normalise and available product should only be used to continue treatment of patients currently treated.
- Novo Nordisk will limit the supply of the starting dose for Ozempic (0.25 mg), which is expected to limit the initiation of new patients, to mitigate the increasing demand on the maintenance doses (Ozempic 0.5 mg and 1 mg). It is recommended to limit initiations of new patients during the shortage and until the supply situation improves which is expected in Q1 2024.
- In case Ozempic or Victoza is not available for patients currently treated with one of these respective products, patients should be safely switched to another injectable GLP-1 RA, or other suitable alternative based on your clinical judgement.

Background

Ozempic and Victoza are 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.

Victoza is also indicated for adolescents and children aged 10 years and above with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise.

Any other use, including for overweight/obesity treatment, represents off-label use and currently places the availability of Ozempic and Victoza for the indicated population at high risk.

Call for reporting

Adverse events including medication errors relating to Ozempic and Victoza should be reported to Novo Nordisk [contact details to be updated by affiliate] or to local authorities [to be modified according to national requirements].

Company contact point

Further information can be obtained by contacting <local Novo Nordisk affiliate contact details to be added by affiliate>.

Novo Nordisk recognises the uncertainty and concern this is causing people living with type 2 diabetes mellitus. Novo Nordisk A/S [affiliate to include country specific information to reflect global or local company name] will continue to provide updates on this supply situation to your local health authority as new information becomes available. Novo Nordisk is working diligently to manage supply of Ozempic and Victoza 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

Medical Director

Communication Plan for Direct Healthcare Professional Communication

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Ozempic (semaglutide) and Victoza (liraglutide)
Marketing authorisation holder(s)	Novo Nordisk A/S
Safety concern and purpose of the communication	<p>Increased overall demand for Ozempic and Victoza injectable glucagon-like peptide-1 receptor agonists (GLP-1 RAs) coupled with capacity constraints at some of our manufacturing sites have led to shortages, including out-of-stock situations. In addition, to facilitate increasing supply of Ozempic, Novo Nordisk decided to temporarily reduce the supply of Victoza. The shortage situation for Ozempic and Victoza will deteriorate in Q4 2023.</p> <p>For Ozempic, intermittent shortages are expected throughout 2024. For Victoza, shortages are expected at least until Q2 2024. The supply shortage is not related to a quality defect of the products or a safety issue.</p>
DHPC recipients	Target group for this letter is general physicians and specialists that treat patients with diabetes (e.g., endocrinologists). Adding pharmacists or other health care providers to the recipients will be determined in conjunction with each national competent authority as needed.
Member States where the DHPC will be distributed	All members states will be contacted but DHPC letter will only be distributed in agreement with each national competent authority as not all countries may be impacted by shortages.
Timetable	Date
DHPC and communication plan (in English) agreed by CHMP	31 Oct 2023
Submission of translated DHPCs to the national competent authorities for review	01 – 08 Nov 2023
Agreement of translations by national competent authorities	~1-3 days dependent upon respective NCA
Dissemination of DHPC	1-3 days after final agreement with NCA