

8 December 2023 EMA/291134/2023 Rev 1.<sup>1</sup>

Shortage of Victoza (liraglutide)  pre-filled pens (6 mg/ml)	
Indication	Victoza is a medicine used in addition to diet and exercise in adults and children from 10 years of age who have type 2 diabetes.  Victoza is used:  on its own when use of metformin (another medicine for type 2 diabetes) is not recommended;  as an 'add-on' to other diabetes medicines.  The active substance in Victoza, liraglutide, is a 'GLP-1 receptor agonist' (GLP-1 RA).
Reason for shortage	There has been an increase in demand for Victoza and delays in production which have also led to the release of some orders being delayed. This has led to supply shortages. In addition, the company has decided to temporarily reduce the production of Victoza to help increase the production of another GLP-1 RA, Ozempic. As a result, shortages of Victoza are expected at least until Q2 2024.  The supply shortage is not related to a quality defect of the product or a safety issue.
Member States affected <sup>2</sup>	The shortage affects some of the Member States where the product is marketed.  For additional information consult your country's <u>shortage register</u> or contact your <u>national competent authority</u> .
Monitoring of shortage	EMA's <u>SPOC working party</u> <sup>3</sup> is closely monitoring the supply situation and engaging with the marketing authorisation holder and other stakeholders to facilitate measures to mitigate the impact of the supply shortage.
Information for healthcare professionals	<ul> <li>An increase in demand for Victoza and delays in production have led to supply shortages, which have been worsened by the company's decision to temporarily reduce the production of Victoza.</li> <li>The shortages are expected to continue until at least Q2 2024.</li> <li>Healthcare professionals should not start any new patients on Victoza until at least Q2 2024, when supply is expected to normalise.</li> <li>Available supplies should only be used to continue treatment of patients currently on Victoza.</li> </ul>

 $<sup>^{\</sup>mathrm{1}}$  This document was modified on 8 December 2023 to reflect the latest DHPC.

 $<sup>^2</sup>$  This information may change. For up-to-date information about the status of a medicine shortage in a particular Member State, contact the national competent authority.

<sup>&</sup>lt;sup>3</sup> The <u>SPOC working party</u> is responsible for monitoring and reporting events that could affect the supply of medicines in the EU. Summaries of the SPOC working party meetings can be found on <u>EMA's website</u>.



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	<ul> <li>If Victoza is not available for patients currently using Victoza, healthcare professionals should switch these patients to another injectable GLP-1 RA or another suitable alternative based on your clinical judgement.</li> <li>A delay in switching may result in patients missing the required doses, which could have clinical consequences such as hyperglycaemia.</li> <li>A direct healthcare professional communication (DHPC) has been sent to relevant healthcare professionals and is also available on the EMA website.</li> <li>Additional advice may be available from your country's national shortage register or national competent authority.</li> </ul>
Information for patients	<ul> <li>An increase in demand for Victoza and delays in production have led to supply shortages, which have been worsened by the company's decision to temporarily reduce the production of Victoza.</li> <li>The shortages are expected to continue until at least Q2 2024.</li> <li>If you are at risk of running out of Victoza, you may need to switch to another treatment (injectable GLP-1 RA). You should make an appointment with your healthcare professional to discuss the need to switch.</li> <li>A delay in switching may cause you to miss doses, which could lead to high blood sugar levels. If you have any questions, speak to your doctor or pharmacist.</li> <li>Additional advice may be available from your country's national shortage register or national competent authority.</li> </ul>
Status	Ongoing