

24 August 2023 EMA/335464/2023 Rev.1¹

Shortage of Saxenda (liraglutide) 6 mg/ml solution for injection in pre-filled pens	
Indication	 Saxenda is a medicine used along with diet and increased physical activity to help manage weight in: adults who have obesity (a body-mass index – BMI – of 30 or more); adults who are overweight (have a BMI between 27 and 30) and have weight-related complications such as type 2 diabetes, abnormally high levels of fat in the blood, high blood pressure or obstructive sleep apnoea (frequent interruption of breathing during sleep); adolescents from 12 years of age who have a BMI of 30 or more (obesity) and who weigh more than 60 kg.
Reason for shortage	There has been an increase in demand for Saxenda which has led to intermittent supply shortages. Shortages are expected to be resolved by the end of March 2024 in most affected countries except Finland, where they may continue until the end of 2024. The supply shortage is not related to a quality defect of the product or a safety issue.
Member States affected ²	Finland, Germany, Norway and Sweden.
Monitoring of shortage	EMA's <u>SPOC working party</u> ³ is closely monitoring the supply situation and engaging with the marketing authorisation holder and other stakeholders to identify measures to mitigate the impact of the supply shortage.
Information for healthcare professionals	 An increase in demand for Saxenda has led to intermittent supply shortages that are expected to continue through to March 2024 in most affected countries. In Finland they may last until the end of 2024. Healthcare professionals should ensure that patients at risk of running out of Saxenda are switched in time to a suitable alternative

 $^{^{\}mathrm{1}}$ This document was modified on 6 February 2024 to update information on the expected date of resolution.

² This information may change. For up-to-date information about the status of a medicine shortage in a particular EU/EEA Member State, consult the <u>national shortage register</u> or contact the <u>national competent authority</u>.

³ 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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	 based on their clinical judgement. Additional advice may be available from your country's <u>national</u> <u>shortage register</u> or <u>national competent authority</u>.
Information for patients	 An increase in demand for Saxenda has led to intermittent supply shortages that are expected to continue through to March 2024 in most affected countries. In Finland they may last until the end of 2024. If you are at risk of running out of Saxenda you should make an appointment with your healthcare professional to discuss switching to a suitable alternative. If you have any questions, speak to your doctor or pharmacist. Additional advice may be available from your country's national shortage register or national competent authority.
Status	Ongoing