



8 December 2023  
EMA/492446/2023 Rev.2<sup>1</sup>

## Shortage of Ozempic (semaglutide) Solution for injection 1 mg, 0.5 mg, 0.25 mg prefilled pen<sup>2</sup>

<b>Indication</b>	<p>Ozempic is a diabetes medicine used with diet and exercise to treat adults whose type 2 diabetes is not satisfactorily controlled.</p> <p>Ozempic can be used on its own in patients who cannot take metformin (another diabetes medicine). It can also be used as an 'add-on' to other diabetes medicines.</p> <p>The active substance in Ozempic, semaglutide, is a GLP-1 receptor agonist (GLP-1 RA).</p>
<b>Reason for shortage</b>	<p>Increased demand for Ozempic coupled with capacity constraints at some of the manufacturing sites have led to shortages.</p> <p>Although the company is taking mitigating measures, the shortage is expected to worsen in December 2023 and continue throughout 2024. It is uncertain when supplies will be sufficient to fully meet current demand.</p> <p>The supply shortage is not related to a quality defect of the product or a safety issue.</p>
<b>Member States affected</b>	<p>All EU Member States where the product is currently marketed.</p> <p>For accurate information about the status of a medicine shortage in a particular Member State, consult the <a href="#">national shortage register</a> or <a href="#">national competent authority</a>.</p>
<b>Monitoring of shortage</b>	<p>EMA's <a href="#">SPOC working party</a><sup>3</sup> 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.</p> <p>Summaries of the SPOC working party meetings can be found on <a href="#">EMA's website</a>.</p>

<sup>1</sup> This document was modified on 13 March 2023 and 8 December 2023 to reflect the latest DHPC and to correct the marketed and affected doses.

<sup>2</sup> The 2 mg strength is authorised but not marketed anywhere in the EU/EEA.

<sup>3</sup> The [SPOC working party](#) is responsible for monitoring and reporting events that could affect the supply of medicines in the EU.



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<b>Information to healthcare professionals</b>	<ul style="list-style-type: none"> <li>• Increased demand for Ozempic coupled with capacity constraints at some of the manufacturing sites have led to shortages which are expected to worsen in December 2023 and continue throughout 2024.</li> <li>• The company has limited the supply of the 0.25 mg starting dose for Ozempic. This will limit the number of new patients starting treatment and ensure that maintenance doses can be used for existing patients.</li> <li>• If Ozempic is not available, patients currently using Ozempic may need to be safely switched 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>• Use outside its authorised use, such as for weight management, is considered off-label and affects the availability of the medicine to treat patients with type 2 diabetes.</li> <li>• An updated direct healthcare professional communication (DHPC) has been sent to relevant healthcare professionals and is also available on the <a href="#">EMA website</a>.</li> <li>• Additional advice may be available from your country's <a href="#">national shortage register</a> or <a href="#">national competent authority</a>.</li> </ul>
<b>Information to patients</b>	<ul style="list-style-type: none"> <li>• Increased demand for Ozempic coupled with capacity constraints at some of the manufacturing sites have led to shortages which are expected to worsen in December 2023 and continue throughout 2024.</li> <li>• The company has limited the supply of the 0.25 mg starting dose for Ozempic. This will limit the number of new patients starting treatment and ensure that maintenance doses can be used for existing patients.</li> <li>• If you are already being treated with Ozempic and the medicine is not available, you may need to switch to another treatment. 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.</li> <li>• Use outside its authorised use, such as for weight management, is considered off-label and affects the availability of the medicine to treat patients with type 2 diabetes.</li> <li>• If you have any questions, speak to your doctor or pharmacist.</li> <li>• Additional advice may be available from your country's <a href="#">national shortage register</a> or <a href="#">national competent authority</a>.</li> </ul>
<b>Status</b>	Ongoing