



19 October 2022
EMA/798839/2022 Rev.1¹

Shortage of Ozempic (semaglutide) Solution for injection 1 mg, 0.5 mg, 0.25 mg prefilled pen²

Indication	<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>
Reason for shortage	<p>There has been an increase in demand for Ozempic which has led to supply shortages that are expected to continue throughout 2023. While supply will continue to increase, it is uncertain when it 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>
Member States affected³	<p>Potentially all EU Member States where the product is currently marketed.</p>
Information to healthcare professionals	<ul style="list-style-type: none">• An increase in demand for Ozempic has led to supply shortages that are expected to continue throughout 2023.• Healthcare professionals should ensure that patients at risk of running out of Ozempic are switched in time to another glucagon-like peptide-1 receptor agonist or other suitable alternatives based on their clinical judgement.• A delay in switching may result in patients missing the required doses, which may have clinical consequences such as hyperglycaemia.• Any use of Ozempic outside its authorised indication, such as for weight management, represents off-label use and puts the availability

¹ This document was modified on 13 March 2023 to reflect the latest DHPC and to correct the marketed and affected doses.

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

³ This information may change. For accurate information about the status of a medicine shortage in a particular Member State the national competent authority should be contacted.



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	<p>of the medicine for the indicated population at risk.</p> <ul style="list-style-type: none"> • An updated direct healthcare professional communication (DHPC) has been sent to relevant healthcare professionals and is also available on the EMA website. • Additional advice, including information on suitable alternatives, may be available from the national competent authority.
Information to patients	<ul style="list-style-type: none"> • An increase in demand for Ozempic has led to supply shortages that are expected to continue throughout 2023. • If you are at risk of running out of Ozempic you should make an appointment with your healthcare professional to discuss switching to a suitable alternative. • A delay in switching may result in patients missing the required doses, which may lead to high blood sugar levels. • Ozempic should not be used outside its authorised use, such as for weight management, as this could affect the availability of the medicine to treat patients with type 2 diabetes. • Additional advice may be available from the national competent authority.
Status	Ongoing