



EMA/283174/2023 Rev. 1

Update of 22 January 2024:

The shortage affecting Rybelsus has been resolved and the below information and recommendations which were issued during the shortage no longer apply.

11 July 2023

**Shortage of Rybelsus (semaglutide)
3, 7 and 14 mg tablets**

Indication	<p>Rybelsus is a diabetes medicine used to control blood glucose (sugar) levels in adults whose type 2 diabetes is not controlled well enough.</p> <p>It can be used on its own when metformin (another medicine for diabetes) cannot be used, or in combination with other diabetes medicines.</p> <p>It should be used with an appropriate diet and physical exercise.</p>
Reason for shortage	<p>There has been an increase in the demand for Rybelsus which is expected to lead to intermittent shortages in some EU Member States. The situation is expected to last until the end of 2023.</p>
Member States affected¹	<p>The shortage affects some of the Member States where the product is marketed: Belgium, Bulgaria, Croatia, Czechia, Estonia, Finland, Hungary, Latvia, Lithuania, Norway, Poland, Romania, Slovenia, Sweden.</p>
Monitoring of shortage	<p>EMA's SPOC working party² 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>In addition, the company that holds the marketing authorisation for Rybelsus will increase the packaging</p>

¹ This information may change. For accurate information about the status of a medicine shortage in a particular Member State, please consult the [national shortage register](#).

² The [SPOC working party](#) 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 [EMA's website](#).



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	<p>capacity in August 2023 to increase supplies and address demand from September 2023 onwards.</p>
Information to healthcare professionals	<ul style="list-style-type: none">• There has been an increase in demand for Rybelsus which is expected to lead to intermittent shortages in some EU Member States.• The situation is expected to last until the end of 2023.• Healthcare professionals should ensure that patients at risk of running out of Rybelsus are switched in time to another glucagon-like peptide-1 (GLP-1) receptor agonist or other suitable alternatives based on their clinical judgement.• A delay in switching to an alternative treatment may result in patients missing the required doses, which may have clinical consequences such as hyperglycaemia.• Any use of Rybelsus outside its authorised indication, such as for weight management, represents off-label use and puts the availability of the medicine for the indicated population at risk.• Additional advice may be available from your national shortage register.
Information to patients	<ul style="list-style-type: none">• The demand for Rybelsus in 2023 is higher than expected. This may lead to intermittent shortages of the medicine in some EU countries.• The situation is expected to last until the end of 2023.• The packaging capacity for Rybelsus will be increased in August 2023. This will help to meet the increase in demand from September 2023 onwards.• If you are at risk of running out of Rybelsus, you should make an appointment with your healthcare professional to discuss switching to a suitable alternative.• A delay in switching to an alternative treatment may cause you to miss the required doses, which may lead to high blood sugar levels.• Rybelsus 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.• If you have questions about your treatment with Rybelsus, please speak with your doctor or pharmacist.• Additional advice may be available from your national shortage register.