



24 August 2023
EMA/334883/2023

Shortage of Tresiba (insulin degludec) pre-filled pens (100 and 200 units/ml)	
Indication	Tresiba is used to treat type 1 and type 2 diabetes in adults and children aged 1 to 18 years of age.
Reason for shortage	There has been a delay in the production of Tresiba at some of the company's sites. This has led to intermittent supply shortages for Tresiba that are expected to continue until the end of 2023 in some EU Member States.
Member States affected¹	Austria, Belgium, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Romania, Spain, and Sweden.
Monitoring of shortage	EMA's SPOC working party ² 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	<ul style="list-style-type: none">• Production capacity limitations have led to intermittent supply shortages that are expected to continue until the end of 2023 in some EU Member States.• The shortage concerns 100 and 200 units/ml solution for injection in pre-filled pens (FlexTouch). The cartridges of Tresiba solution for injection (3ml of 100 units/ml) remain available.• Healthcare professionals should ensure that patients at risk of running out of Tresiba are switched to a suitable alternative in time.• Additional advice may be available from your country's national shortage register or national competent authority.
Information for patients	<ul style="list-style-type: none">• Production capacity limitations have led to intermittent supply shortages that are expected to continue until the end of 2023.

¹ 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.

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](#).



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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- The shortage concerns 100 and 200 units/ml solution for injection in pre-filled pens (FlexTouch). The cartridges of Tresiba solution for injection (3ml of 100 units/ml) remain available.
- If you are at risk of running out of Tresiba, your doctor will discuss with you the need to switch 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