



22 February 2024
EMA/52182/2024

Shortage of Eldisine (vindesine) 5mg, powder for solution for injection into a vein	
Indication	Eldisine is used to treat types of blood cancer such as acute lymphoblastic leukaemia and chemotherapy-refractory lymphoma, as well as certain solid tumours, such as cancer of the breast, oesophagus (the tube that connects the mouth to the stomach), upper aerodigestive tract (airways of the head and neck) and lungs.
Reason for shortage	<p>The company that produces Eldisine's active substance cannot produce new batches using the current manufacturing process.</p> <p>The company is developing a new process for manufacturing the active substance, which is expected to be approved in 2024.</p> <p>A shortage of Eldisine is expected to last until the end of 2024.</p> <p>The shortage is not related to a quality defect of the medicine or a safety issue.</p>
Member States affected	<p>The shortage affects all Member States where the product is marketed or available.</p> <p>For up-to-date information about the status of this shortage in a particular Member State, consult the national shortage register or contact the national competent authority.</p>
Monitoring of shortage	<p>EMA's SPOC working party¹ is closely monitoring the supply situation and engaging with the marketing authorisation holder to follow up on the measures to mitigate the impact of the supply shortage, including the possibility of importing the active substance from outside the EU.</p> <p>Summaries of the SPOC working party meetings can be found on EMA's website.</p>
Information to healthcare professionals	<ul style="list-style-type: none">• Due to manufacturing issues, there is a shortage of Eldisine in all Member States where the medicine is marketed or available.• Healthcare professionals should check with their national competent authority if new patients can be started on Eldisine.• Before starting treatment, healthcare professionals should ensure sufficient supplies are available.

¹ 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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	<ul style="list-style-type: none">• For patients who are already receiving Eldisine treatment, doctors should consider alternative treatment options if Eldisine is unavailable.• As there is no other vindesine-containing medicine available in the EU, doctors should consider other medicines, taking into consideration local and national guidance.• For additional information consult your country's shortage register or contact your national competent authority
Information to patients and carers	<ul style="list-style-type: none">• Due to manufacturing issues, there is a shortage of Eldisine in all Member States where the medicine is marketed or available.• If you are going to start treatment, your doctor will get guidance from the national competent authority on whether new patients can be started on Eldisine. Before starting your treatment, they will ensure sufficient supplies are available.• If you are using Eldisine and it is no longer available, your doctor will discuss suitable treatment alternatives with you.• If you have any questions, speak to your doctor or pharmacist.• For additional information, consult your country's shortage register or contact your national competent authority
Status	Ongoing