



06 March 2024  
EMA/57002/2024

<b>Shortage of fludarabine Concentrate for solution for injection or infusion, 25 mg/ml</b>	
<b>Indication</b>	Fludarabine is used to treat adults with chronic lymphocytic leukaemia.
<b>Reason for shortage</b>	<p>A general shortage of the active pharmaceutical ingredient and an unexpected increase in demand for fludarabine medicines have led to a shortage at different manufacturers in several European countries.</p> <p>The shortage is not related to a quality defect of the product or a safety issue.</p> <p>The shortage is expected to last until the end of March 2024.</p>
<b>Member States affected</b>	<p>The shortage affects several European countries.</p> <p>This information may change. For up-to-date information about the status of a medicine shortage in a particular EU/EEA Member State, consult the <a href="#">national shortage register</a> or contact the <a href="#">national competent authority</a>.</p>
<b>Monitoring of shortage</b>	<p>EMA's <a href="#">SPOC working party</a><sup>1</sup> is closely monitoring the supply situation.</p> <p>Summaries of the SPOC working party meetings can be found on <a href="#">EMA's website</a>.</p>
<b>Information to healthcare professionals</b>	<ul style="list-style-type: none"><li>• Current production capacity cannot meet an unexpected increase in the demand for fludarabine medicines. This has led to shortages of fludarabine in several European countries.</li><li>• Before starting treatment, healthcare professionals should ensure sufficient supplies are available and check with their <a href="#">national competent authority</a> whether they can start new patients on fludarabine.</li><li>• In case of supply shortages, healthcare professionals should consider alternative treatment options for patients already receiving fludarabine treatment, taking into consideration local and national guidance.</li><li>• For additional information healthcare professionals should consult their country's <a href="#">shortage register</a> or contact their national competent authority.</li></ul>

<sup>1</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 patients and carers</b>	<ul style="list-style-type: none"><li>• Production capacities for fludarabine medicines cannot meet an increase in demand. This has led to a shortage of fludarabine in several European countries.</li><li>• Your doctor will check that sufficient supplies are available before starting treatment.</li><li>• In case fludarabine is unavailable, your doctor will discuss possible alternatives with you.</li><li>• If you have any questions, speak to your doctor or pharmacist.</li><li>• For additional information, please consult your country's <a href="#">shortage register</a> or contact your <a href="#">national competent authority</a>.</li></ul>
<b>Status</b>	<ul style="list-style-type: none"><li>• Ongoing</li></ul>