



23 June 2017
EMA/371236/2017 Rev. 2

Shortage of Depocyte (cytarabine) suspension for intrathecal injection	
Indication	Depocyte is a medicine used to treat lymphomatous meningitis.
Reason for shortage	<p>In December 2016 at the manufacturing site for Depocyte, several batches failed standard quality testing.</p> <p>The affected batches were not released, and manufacturing was temporarily suspended, causing a supply shortage of the medicine. Any product that was already on the market has not been affected.</p> <p>Stocks have now run out in some European countries and it is expected that by the end of June 2017 any remaining Depocyte stocks will have been exhausted across all European countries where it is marketed. It is not known when European countries will be re-supplied with Depocyte.</p>
Member States affected¹	<p>By the end of June, all EU Member States where Depocyte is currently marketed are expected to be out of stock:</p> <p>Austria, Belgium, Czech Republic, Denmark, Germany, Ireland, Italy, Iceland, Portugal, Poland, France, Finland, the Netherlands, Slovakia, Slovenia, Spain and Sweden and the United Kingdom. Norway is expected to be out of stock by mid-June.</p>
Information for healthcare professionals	<ul style="list-style-type: none">• A manufacturing issue is affecting the supply of Depocyte and stocks will run out by the end of June 2017 across all European countries.• Healthcare professionals have been informed in writing about the stock-out.• Patients should be transferred to a suitable alternative such as immediate-release cytarabine, where available. The treating physician must check whether alternative products are approved for intrathecal use for the treatment of lymphomatous meningitis. Not all strengths of immediate-release cytarabine include this route of administration and/or indication.

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](#).



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	<ul style="list-style-type: none">• No new patients should be started on treatment with Depocyte.• When placing an order, healthcare professionals should clarify that this relates to an existing patient and limit their order to 2 vials per patient.• Additional advice may be available from the national competent authority.
Information for patients	<ul style="list-style-type: none">• A manufacturing issue is affecting the supply of Depocyte and stocks will run out by the end of June 2017 across all European countries.• To manage remaining stocks efficiently, doctors will not start any new patients on Depocyte. Instead, doctors will consider a suitable alternative.• For existing patients, doctors may switch treatment to a suitable alternative.• Patients who have any questions should speak to their doctor or pharmacist.• Additional advice may be available from the national competent authority.
Status	Ongoing