



15 March 2019  
EMA/131667/2019 Rev.2

<b>Shortage of Nulojix (belatacept) solution for infusion</b>	
<b>Indication</b>	Nulojix is used in adults to prevent the body from rejecting a transplanted kidney.
<b>Reason for shortage</b>	Since March 2017 supply of Nulojix has been disrupted due to an inability to produce as much medicine as required to meet current demands while the company changes its manufacturing process. The transition to the new manufacturing process is ongoing and although supplies have improved some restrictions have to remain in place until at least the third quarter of 2020.
<b>Member States affected<sup>1</sup></b>	The shortage affects all the countries where Nulojix is marketed. In the EU these are: Austria, Denmark, France, Germany, Hungary, Ireland, Italy, the Netherlands, Norway, Poland, Spain, Sweden, and the United Kingdom.
<b>Information for healthcare professionals</b>	<ul style="list-style-type: none"><li>• A letter from the marketing authorisation holder, Bristol-Myers Squibb, has been sent to healthcare professionals in the affected countries to inform them of the updated measures to be taken during the shortage, which is expected to last at least until the third quarter of 2020.</li><li>• New patients can now be started on Nulojix but only if enough supplies are available. Therefore, before a new patient is started on Nulojix, a member of the transplant team should contact the marketing authorisation holder, Bristol-Myers Squibb, to confirm that adequate supplies are available.</li><li>• Additional advice may be available from the <a href="#">national competent authority</a> and from the marketing authorisation holder.</li></ul>
<b>Information for patients</b>	<ul style="list-style-type: none"><li>• Nulojix remains in short supply. The shortage is expected to last at least until the third quarter of 2020.</li><li>• New patients can now be started on Nulojix, but only if enough supplies are available.</li><li>• If you are due to start Nulojix a member of the transplant team will contact the manufacturer to confirm that adequate</li></ul>

<sup>1</sup> 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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	<p>supplies are available.</p> <ul style="list-style-type: none"><li>• Patients who have any questions should speak to their doctor or pharmacist.</li><li>• Additional advice may be available from the <a href="#">national competent authority</a>.</li></ul>
<b>Status</b>	Ongoing