



EMA/439578/2023 Rev.5<sup>1,2</sup>

**Update of 29 September 2023:**

The shortage affecting Nulojix has been resolved and the below information and recommendations which were issued during the shortage no longer apply.

17 January 2022

<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 some restrictions will remain in place until the third quarter of 2022.
<b>Member States affected<sup>3</sup></b>	The shortage affects most countries where Nulojix is marketed. In the EU these are: Austria, Denmark, France, Germany, Hungary, Italy, the Netherlands, Northern Ireland, Norway, Spain and Sweden.
<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 that the shortage will last longer than expected (until third quarter of 2022) and that the measures previously agreed should continue to be followed.</li><li>• New patients can 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</li></ul>

<sup>1</sup> Information has been revised following a DHPC informing healthcare professionals that the shortage will last longer than previously anticipated.

<sup>2</sup> The box announcing the resolution of the shortage has been added (29 September 2023)

<sup>3</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.

## Shortage of Nulojix (belatacept) solution for infusion

	<p>holder.</p> <ul style="list-style-type: none"><li>• A direct healthcare professional communication (DHPC) informing about the new timelines has been sent to relevant HCPs and is also available on <a href="#">the EMA website</a>.</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 until the third quarter of 2022.</li><li>• New patients can be started on Nulojix, but only if enough supplies are available.</li><li>• If you are due to start treatment with Nulojix a member of the transplant team will contact the manufacturer to confirm that adequate supplies are available.</li><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