Bristol Myers Squibb™

IMPORTANT INFORMATION
FOR HEALTHCARE PROFESSIONALS AND PATIENTS

17 January 2022

NULOJIX (belatacept)
Further extension of the temporary restriction in supply up until 3Q 2022 in the United Kingdom (Great Britain & Northern Ireland)

Dear Healthcare Professional,
Bristol Myers-Squibb (BMS) in agreement with the European Medicines Agency and the Medicines & Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

Summary

- The temporary restriction in supply of Nulojix (belatacept) will be further extended until 3Q 2022.

- Due to the restriction in supply, Nulojix can only be prescribed to new patients if the following two criteria are met:
    1. Nulojix is the best treatment option for the patient
    2. BMS has confirmed that supplies are adequate for new and existing patients.

- Before initiating Nulojix treatment in new patients, BMS Medical Information should be contacted to confirm that adequate supplies are available. See contact details below.

Background on the supply shortage
Since March 2017, distribution of Nulojix has been restricted to existing patients worldwide. The supply shortage is related to a temporary production capacity issue. It is not related to a quality defect of the product or a safety issue. The temporary restriction in supply is further extended to allow for the final transition to a new, higher capacity manufacturing process. Nulojix manufactured with the new process is expected to be available in 3Q 2022, a communication will be sent to Healthcare Professionals ahead of its distribution.

Management of the supply shortage
In the United Kingdom, prescribers were invited to cooperate in avoiding initiation of a Nulojix-based regimen in new patients, unless the above criteria are met.

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Indication
NULOJIX, in combination with corticosteroids and a mycophenolic acid (MPA), is indicated for prophylaxis of graft rejection in adult recipients of a renal transplant (see section 5.1 of the SmPC for data on renal function).

For further information on belatacept, please refer to the approved product information available at:

Great Britain
https://www.medicines.org.uk/emc/product/4685/smpc#gref

Northern Ireland
https://www.emcmedicines.com/en-gb/northernireland/medicine?id=44dd6c99-6091-4064-a6eb-255ca6d696f6&type=smpc

Call for Reporting
Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason

It is easiest and quickest to report ADRs online via the Yellow Card website - https://yellowcard.mhra.gov.uk/ or via the Yellow Card app available from the Apple App Store or Google Play Store.

Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing yellowcard@mhra.gov.uk
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- by downloading and printing a form from the Yellow Card website (see link above)

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

Adverse events should also be reported to Bristol-Myers Squibb Medical Information on 0800 731 1736 or medical.information@bms.com.

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Company contact point
If you have further questions or require information, please contact Bristol Myers Squibb Medical Information by phone on 0800 731 1736 or via email medical.information@bms.com.

Yours Sincerely,

H fathi (Jan 14, 2022 14:55 GMT)

Dr. Hosnieh Fathi, Director, Disease Area Head, Innovative Medicines- Medical UK & Ireland

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