Bristol-Myers Squibb Pharmaceuticals Limited

Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH
Tel 01895 523000 Fax 01895 523010

March 2019

Direct Healthcare Professional Communication –
**Nulojix® (belatacept) 250 mg powder for concentrate for solution for infusion**
**Update on the temporary restriction in supply (initiated in March 2017)**

Dear Healthcare Professional,

Bristol Myers-Squibb in agreement with the European Medicines Agency (EMA) and the Medicines and Healthcare Products Regulatory Agency (MHRA) would like to inform you of the following for NULOJIX® (belatacept):

**Summary**

- **Starting 11 March 2019, Nulojix can 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, a member of the transplant team should contact BMS Medical Information to confirm that adequate supplies of Nulojix are available, (see contact details below).**

- **The requirement to confirm available supplies before initiating treatment for new patients is expected to remain in place until September 2020.**

**Background on the supply shortage**

Since March 2017, distribution of Nulojix has been restricted to existing patients worldwide. Only patients with an urgent medical need for Nulojix, who had exhausted all other options, were permitted to start Nulojix. 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. As production of Nulojix returns to normal capacity, restrictions can be eased to allow new patients to be treated with Nulojix when the above-mentioned criteria are met.

**Indication**

NULOJIX (belatacept), in combination with corticosteroids and a mycophenolic acid (MPA), is indicated for prophylaxis of graft rejection in adults receiving a renal transplant (see section 5.1 of the SmPC for data on renal function). It is recommended to add an interleukin (IL)-2-receptor antagonist for induction therapy to this belatacept-based regimen.

**Reporting adverse events**

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

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- 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.
- All suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

It is easiest and quickest to report ADRs online via the Yellow Cards 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)
- search for MHRA Yellow Card in the Google Play or Apple App Store
- 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
- or by downloading and printing a form

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.

***Bristol-Myers Squibb contact information and enquiries***

If you have further questions or require additional information, please contact the BMS Medical Information department - Telephone: 0800 731 1736; Email: medical.information@bms.com.

Kind Regards,

Dr. Faisal Mehmud BSc, MBBChir, MRCP, MFPM
Executive Medical Director, UK & Ireland
Bristol-Myers Squibb Pharmaceuticals Ltd

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