Bristol Myers Squibb™

Date: December 2022

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

ONUREG 300mg Film-coated Tablets (oral azacitidine):
Interim Supply of Northern Ireland (NI) Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: Bristol-Myers Squibb Pharma EEIG (BMS) is currently experiencing supply disruption with ONUREG 300mg Film-coated Tablets (oral azacitidine) in the UK (Great Britain).

To ensure continuity in supply, Bristol-Myers Squibb Pharmaceuticals EEIG (BMS) has obtained approval from the MHRA to supply Northern Ireland (NI) product (batch number N2009CC & N2009CA; 36 packs which is expected to be on the UK (Great Britain) market from November to December 2022.

Please note the following:

- This product is considered licensed in the UK.
- The product from Northern Ireland (NI) has the same formulation as the UK (Great Britain) product
- The product from Northern Ireland (NI) is manufactured according to the same manufacturing process and quality controls as the UK (Great Britain) product.
- There are minor differences between the Northern Ireland (NI) and UK (Great Britain) product information. Key differences are:
    - o Date of authorisation
    - o References to European Medicines Agency (EMA) in the UK(NI) PIL
    - o References to the MHRA in the UK(GB) PIL

  Please ensure the UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are followed.
- Please refer to the UK (Great Britain) approved PIL supplied with the Northern Ireland (NI) packs. Discard the Northern Ireland (NI) leaflet in the pack.
- For additional copies of the leaflet, please refer to https://www.medicines.org.uk/emc/product/14218/smpc or contact the company contact point (see below).
- The MHRA has agreed to an exemption granted in accordance with regulation 266(4)(a) and (b) of the Human Medicines Regulations (HMR) 2012, from the obligation that certain particulars should appear on the outer and immediate packaging of ONUREG 300mg Film-coated Tablets (oral azacitidine) and that the information must be given in English.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.

Bristol-Myers Squibb Pharmaceuticals Limited
ARC Uxbridge
Sanderson Road
New Denham, Denham, Buckinghamshire
UB8 1DH United Kingdom
bms.com/gb

Office +44 (0)1895 523000
Fax +44 (0)1895 523010
Medical Information 0800 731 1736
medical.information@bms.com

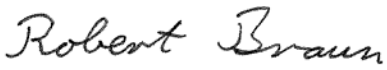
Registered In England 2487574. Registered Office: Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH

Call for reporting
Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website https://www.gov.uk/yellowcard, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effects can also be reported by calling 0800 731 6789 for free.

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

Company contact point
If you have any questions about this letter or require more information about Onureg, please contact the BMS Medical Information department at 0800 731 1736 or via email at medical.information@bms.com.

Yours faithfully,



Robert Braun
Director, Disease Area Head Haematology/Oncology UK/Ireland
Bristol Myers Squib

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Bristol-Myers Squibb Pharmaceuticals Limited
ARC Uxbridge
Sanderson Road
New Denham, Denham, Buckinghamshire
UB8 1DH United Kingdom
bms.com/gb

Office +44 (0)1895 523000
Fax +44 (0)1895 523010
Medical Information 0800 731 1736
medical.information@bms.com

Registered In England 2487574. Registered Office: Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex UB8 1DH