Bristol Myers Squibb™

Direct Healthcare Professional Communication

IMPORTANT INFORMATION

FOR NORTHERN IRELAND HEALTHCARE PROFESSIONALS

Abraxane (paclitaxel albumin), 5mg/ml powder for suspension for injection: supply of Republic of Ireland stock to UK (Northern Ireland) from May 2022 to October 2022

11 May 2022

Dear Healthcare Professional,

Summary: Bristol-Myers Squibb Pharma EEIG (BMS) is currently experiencing a supply disruption with the 100 mg / 20 ml presentation of Abraxane (paclitaxel albumin) in UK (NI).

To ensure continuity of supply, BMS has obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to supply UK (NI) with a batch originally packaged for Ireland (IE) only, batch 1J084D, batch size 700 units. This is expected to be supplied in UK (NI) for the period from May - October 2022.

Please note the following:

- This Ireland batch of product (batch number 1J084D) is considered licensed in UK (NI).
- The product from Ireland (batch number 1J084D) has the same formulation as the product normally supplied in UK (NI).
- The product from Ireland (batch number 1J084D) is manufactured according to the same manufacturing processes and quality controls as the UK (NI) product.
- There are no differences between the IE and the UK (NI) product information texts (Summary of Product Characteristics (SmPC) /Patient Information Leaflet (PIL) / vial label).
- For additional copies of the Package Leaflet (PIL), please refer to https://www.emcmedicines.com/en-gb/northernireland or contact the company contact point (see page 3).
- The MHRA has agreed to an exemption according to Article 63(3) of Council Directive 2001/83/EC, from the obligation that certain particulars should appear on the outer and immediate packaging of Abraxane (paclitaxel albumin) batch number 1J084D.

Please ensure all relevant staff are made aware of the content of this letter.

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Background on the supply shortage

The temporary supply of Abraxane (paclitaxel albumin) IE packs into the UK (NI) market (batch number 1J084D, 700 units) will take place until joint IE/UK (NI) packs are implemented in the next production run (scheduled for September 2022). The UK (NI) market will then be supplied from October 2022 with the new IE/UK (NI) joint packs.

The product folding box on the Ireland batch, 1J084D states that the product is only for the member state of "Ireland", however the package leaflet included in the pack for this batch is in line with the currently approved UK (NI) labelling text (including Adverse Drug Reaction (ADR) reporting information for both UK (NI) and IE). In addition, both IE and UK (NI) have the same marketing authorisation numbers EU/1/07/428/001-002.

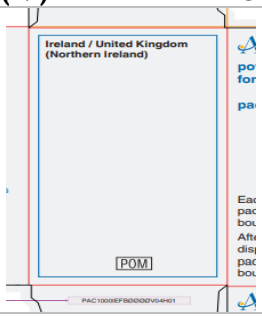
The UK (NI) market was previously supplied with a UK wide pack. Due to Brexit, separation of the UK wide pack into a standalone Great Britain pack and a joint UK (NI)/IE pack was planned with the production run in April 2022 however this has been delayed until September 2022.

Therefore, BMS has obtained approval from the MHRA to release and distribute the Abraxane (paclitaxel albumin) IE pack into UK (NI) as the only difference was the text on the folding box with the market name (see below).

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

UK (Northern Ireland)
https://www.emcmedicines.com/en-gb/northernireland/medicine?id=441628a6-f9f3-482d-b86a-837009139e9e&type=smpc

For further details on the difference between folding box versions please refer to the images below:

IE Folding Box due to be supplied in the UK (NI) market from May 2022 - Oct 2022	Folding Box due for implementation for the IE / UK (NI) market from Oct 2022
	

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Call for Reporting

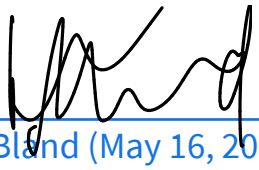
Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website https://yellowcard.mhra.gov.uk/, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, 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.

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

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

Yours sincerely,



Dr Hubert Bland (May 16, 2022 12:43 GMT+1)

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