



16 August 2021

**DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION**

**Hizentra Syringe 20% 5ml/10ml (PLGB 15036-0156): interim supply of US Stock to mitigate supply disruption**

Dear Healthcare Professional,

To ensure continuity in supply, CSL Behring UK Ltd has obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to supply specific batches of US stocks of Hizentra pre-filled syringes to the GB market in place of the Hizentra pre-filled Syringe EU/1/11/687/015 & EU/1/11/687/017 (Converted to PLGB 15036-0156).

**Summary - please note the following:**

- This product is considered licensed in the UK
- The US syringes formulation and quality standards are considered equivalent to the existing UK syringes.
- A letter, addressed directly to patients, is available for healthcare professionals to give out when explaining the issue.
- The US Hizentra syringes available are considered equivalent to the existing Hizentra syringes in the UK.
- Please ensure the UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are followed.
- There is no Braille information on the US pack
- Patients and Health Care Professionals should follow the instructions given in the UK product information and a UK Patient Information Leaflet should be provided with each supply.

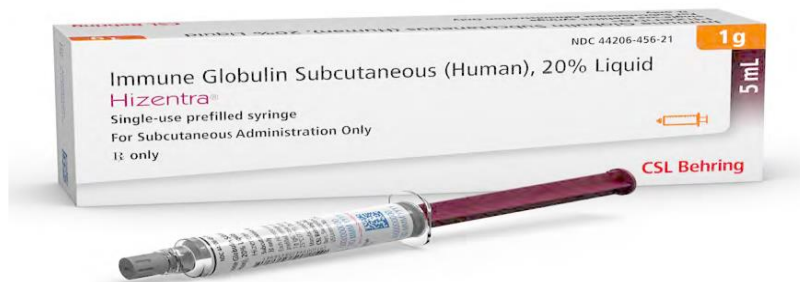
Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to patients. A letter is available to be provided to patients receiving US stock of Hizentra.

The US batch numbers that will be supplied to the UK are as follows: -

Product code: 44012

Batch

numbers: P100124590 / P100147601 / P100196551



Product code: 44025

CSL Behring is a company of CSL Limited

Date of Prep: August 2021

GBR-HIZ-0147

Batch numbers: P100147604 / P100163335 / P100174538



The batches listed above are expected to be on the GB market from September 2021 until approximately June 2022.

#### **Call for reporting**

Healthcare professionals are asked to report suspected adverse reactions to the Yellow Card Scheme. 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 onset of symptoms, treatment dates, product brand name, medical history and any concomitant medication.

#### **Company contact point**

All medical enquiries should be directed to [Medinfo@cslbehring.com](mailto:Medinfo@cslbehring.com)

*Enquires related to supply of pre-filled syringes should be directed to your local CSL Behring Regional Business Manager.*

*For all other enquires please contact:*

#### **Nicky Whiteley**

*National Sales and Commercial Access Manager*

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