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Date: 3<sup>rd</sup> November 2022

## **DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION**

### **Vincristine sulfate 1 mg/1 ml solution for injection (PL 04515/0008) – 2 mg in 2 ml Temporary supply of US stock of Vincristine sulfate Injection, USP 2 mg/2 ml (batch number GD0903AA) to mitigate supply disruption**

Dear Healthcare Professional,

#### **Summary:**

Pfizer UK are experiencing shortages of Vincristine Sulfate 1 mg/ml solution for injection supplied in packs of 2 mg in 2 ml.

Pfizer has obtained agreement from the Medicines and Healthcare products Regulatory Agency (MHRA) to import unlicensed stock of Pfizer Vincristine sulfate Injection, USP 2 mg/2 ml from the USA, to minimise supply disruption until expected replenishment of the UK product supply at the end of February 2023.

#### **Please note the following:**

- The US product is unlicensed in the UK; this means that the imported product has not been given a Marketing Authorisation by the MHRA, it only has a licence from the US FDA.
- The US product is manufactured according to the same manufacturing process, same manufacturing site and has the same formulation as the UK product.
- The benefit-risk profile of the US product is consistent with the UK product.
- There are minor differences between the US and UK product information. Please ensure the UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are followed.

**Differences in presentation:**

	<b>Vincristine sulfate 1 mg/1 ml solution for injection 2 mg in 2 ml (UK licensed product)</b>	<b>Vincristine sulfate Injection, USP 2 mg/2 ml (US product)</b>
MAH	Hospira UK Limited	Hospira, Inc.
Pack size	5 vials	1 vial
Vial seal	Aluminium Seal, Flip-off, 13 mm, Red	Aluminium Seal, Flip-off, 13 mm, Blue
Shelf life	2 years	18 months

For ease of reference, please see a representation of the UK authorised pack and the imported US pack for comparison below:

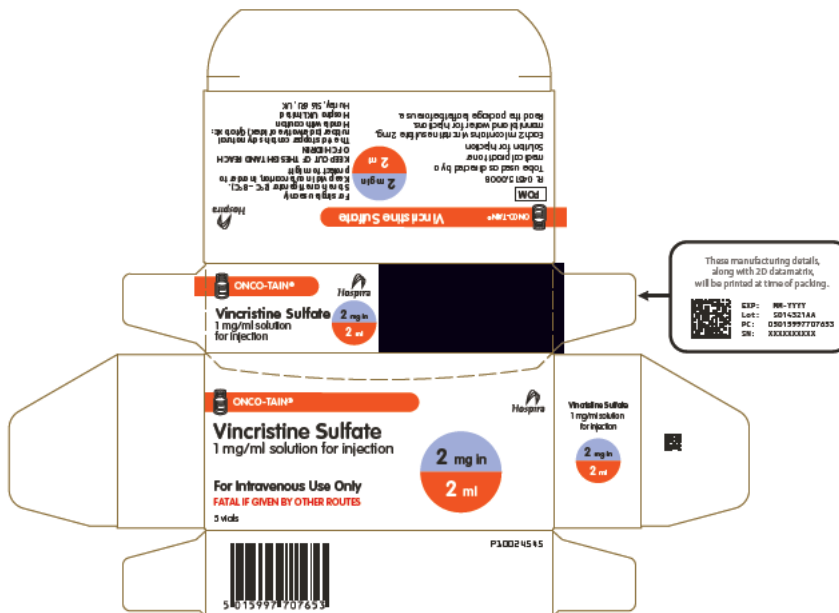


Figure 1: Licensed UK product carton – Vincristine sulfate 1 mg/ 1ml solution for injection 2 mg in 2 ml, PL 04515/0008



Please refer to the Summary of UK Product Characteristics (SPC) for further details.  
<https://products.mhra.gov.uk/product/?product=VINCRISTINE%20SULFATE%201MG%2FML%20INJECTION>

Please note, the Marketing Authorisation Holder remains Hospira UK Limited for this product.

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

### **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, SystemOne, Vision, MiDatabank) for healthcare professionals. Suspected side effect 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, treatment dates, and product brand name.

### **Company contact point**

If you have any questions about this letter or for more information about Vincristine, please contact Pfizer Medical Information on 01304 616161 or <https://www.pfizermedicalinformation.co.uk/en-gb>.

Yours Faithfully,

DocuSigned by:  
*Prasad Velisetty*

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Prasad Velisetty

Medical Director, Hospital, Pfizer UK

November 7, 2022