

**DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION****Calcium Folate 10 mg/ml solution for injection or infusion: supply of the Irish product**

Product	Batch No.	Expiry Date	Batch size
<b>Folinic acid (as calcium folinate) 10 mg/ml solution for injection or infusion</b>	16QC01	08/2022	2550 units

**28 March 2022**

Dear Healthcare Professional,

**Summary:**

To ensure continuity in supply, Fresenius Kabi Limited has obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to supply the above referenced product from the Irish market which is expected to be on the UK market from April to June 2022. These packs are labelled Folinic acid (as calcium folinate) 10 mg/ml solution for injection or infusion, the batch numbers, expiry dates and batch size concerned are noted in the table at the top of this letter.

Please note the following:

- This product is considered licensed in the UK
- The product from Ireland has the same formulation as the UK product
- The product from Ireland is manufactured according to the same manufacturing process and quality controls as the UK product
- There are minor differences between the Irish and UK product information. Differences include the product name, license holder name and address and license number. Details for the Irish product are below and full labelling is available on the next page:
  - The Irish product name is Folinic acid (as calcium folinate) 10 mg/ml solution for injection or infusion.
  - The Licence holder name and address is Fresenius Kabi Deutschland GmbH, Else-Kröner-Straße 1, 61352 Bad Homburg v.d.Höhe, Germany.
  - The Licence number is for the Irish product is PA2059/001/001
- Please ensure the [UK Summary of Product Characteristics](#) (SPC) and [Patient Information Leaflet](#) (PIL) are followed.

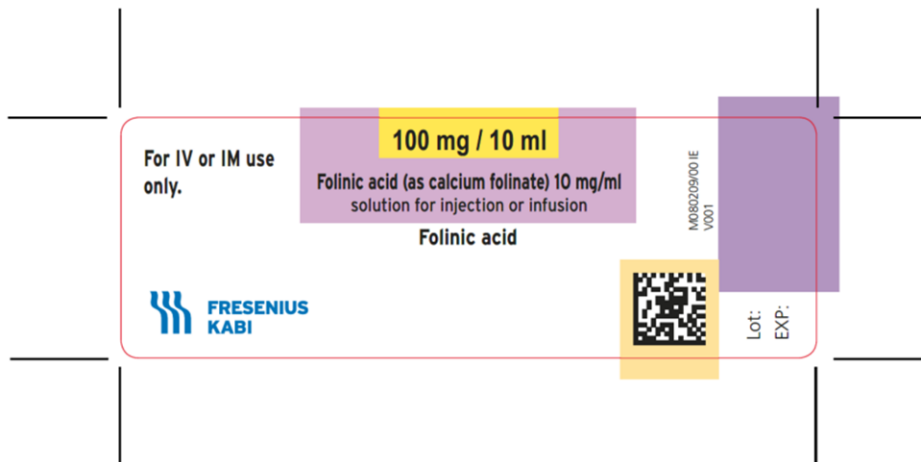


**Fresenius Kabi Limited**  
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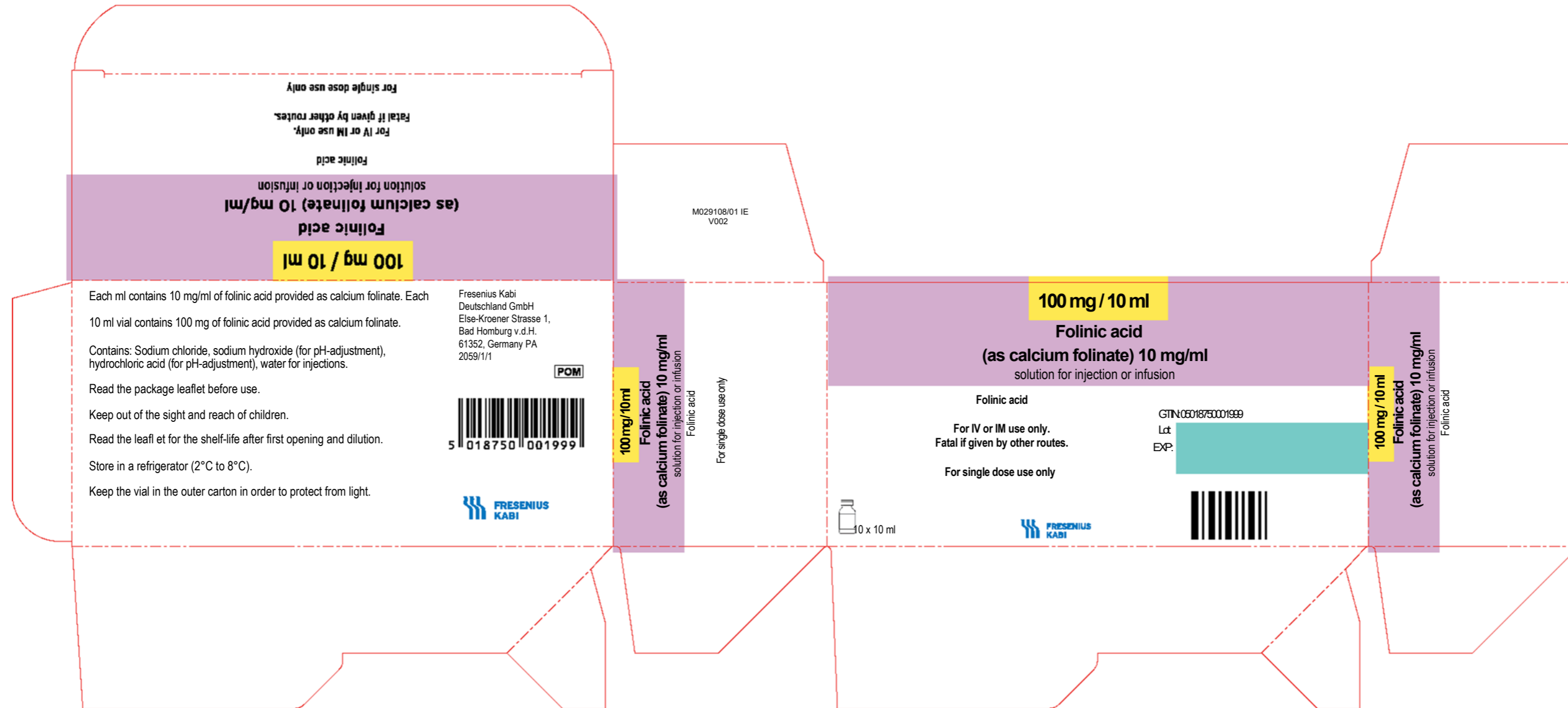
Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to patients.

**Labelling of the Irish product: Folinic acid (as calcium folinate) 10 mg/ml solution for injection or infusion**

**Label:**



Carton:





**Fresenius Kabi Limited**  
Fresenius Kabi Ltd  
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Eastgate Way, Manor Park  
Runcorn, Cheshire, WA7 1NT  
United Kingdom  
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### **Call for reporting**

Healthcare professionals are asked to report 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.

### **Company contact point**

If you have any questions about this letter or require more information about **Calcium folinate 10 mg/ml solution for injection or infusion**, please contact [Medical.Information-UK@fresenius-kabi.com](mailto:Medical.Information-UK@fresenius-kabi.com)

Yours faithfully,

A handwritten signature in black ink that reads "Sree Lakshmi".

**Dr Sree Lella**  
**Senior Regulatory Affairs Officer**  
**Fresenius Kabi Limited**