04 July 2025

Urgent Product Alert

Re: Notification of Typographical Error on Carton for ELOCTATE efmoroctocog alfa (rhu) powder for injection vial and diluent pre-filled syringe
1000 IU (AUST R 210525) – Batch RC2691
2000 IU (AUST R 210524) – Batch RC2587, RC2639
3000 IU (AUST R 210520) – Batch RC2588

TGA Reference Number: RC-2025-RN-00593-1

Sanofi is writing to advise you of a typographical error on the cartons of the **1000 IU, 2000 IU and 3000 IU** powder for injection presentation of ELOCTATE (AUST R 210525, AUST R 210524, AUST R 210520).

What is the Problem?
The active ingredient is incorrectly stated as **eftrenonacog alfa (rhu)** instead of **efmoroctocog alfa (rhu)** on the carton faces. Additionally, on the 3000 IU carton the strength is stated as **2000 IU** instead of **3000 IU** next to the active ingredient name. See Figures 1 to 6 for pictures of the carton labels, indicating the correct and incorrect information.

- The product strength is correctly stated on all faces of the carton in the strength identifier section (coloured bubble).
- The coagulation factor and indication are correctly stated on the carton.
- The vial label and the product leaflet enclosed within the carton are accurate.

What is the Risk?
The error has no impact on the medicine's quality, and ELOCTATE efmoroctocog alfa (rhu) is suitable for ongoing use in the treatment of haemophilia A.

While the labelling error is purely typographical, but it could potentially lead to customer confusion and therefore a delay to administration of a critical medicine.

There is no error on the carton for the 250 IU and 500 IU strengths which correctly state the active ingredient.

What should you do?

- Inspect your stock **immediately** and confirm if you have the impacted batches.
- Affected product in the market may continue to be used in the treatment of haemophilia A, however customers should maintain an awareness of this labelling error, as described above. Patients and HCPs should refer to the **vial label** and product leaflet for the accurate information.
- If you have supplied or transferred any affected product to any patients or other organisations, provide them with a copy of this letter immediately.
- DHL will contact you to confirm receipt of this Urgent Product Alert letter, even if you do not have any affected stock.
- Ensure relevant staff members are informed of this product alert.
- Place this letter in a prominent position for at least one month.
- If you have any questions or concerns about this matter, please contact us on 1800 818 806.

Adverse Event Reporting

Any adverse events which are experienced with ELOCTATE efmoroctocog alfa (rhu) powder for injection vial and diluent pre-filled syringe should be reported by healthcare professionals and patients to Sanofi on 1800 818 806 or ae@sanofi.com. Alternatively, any suspected adverse events can be reported to the TGA at www.tga.gov.au/reportingproblems.

The Australian Product information for ELOCTATE efmoroctocog alfa (rhu) is available at https://www.ebs.tga.gov.au.

If you would like further information regarding ELOCTATE efmoroctocog alfa (rhu) please contact:

- For medical enquiries contact Sanofi Medical Information 1800 818 806
- For enquiries relating to supply contact DHL 1800 322 867

Thank you for your understanding.
Regards,

Electronically signed by:
Mark Rendulic
Reason: Approved to send
Date: Jul 4, 2025 14:06 GMT+10

Mark Rendulic
Australia/New Zealand Quality Head

Figure 1: 1000 IU Carton Label

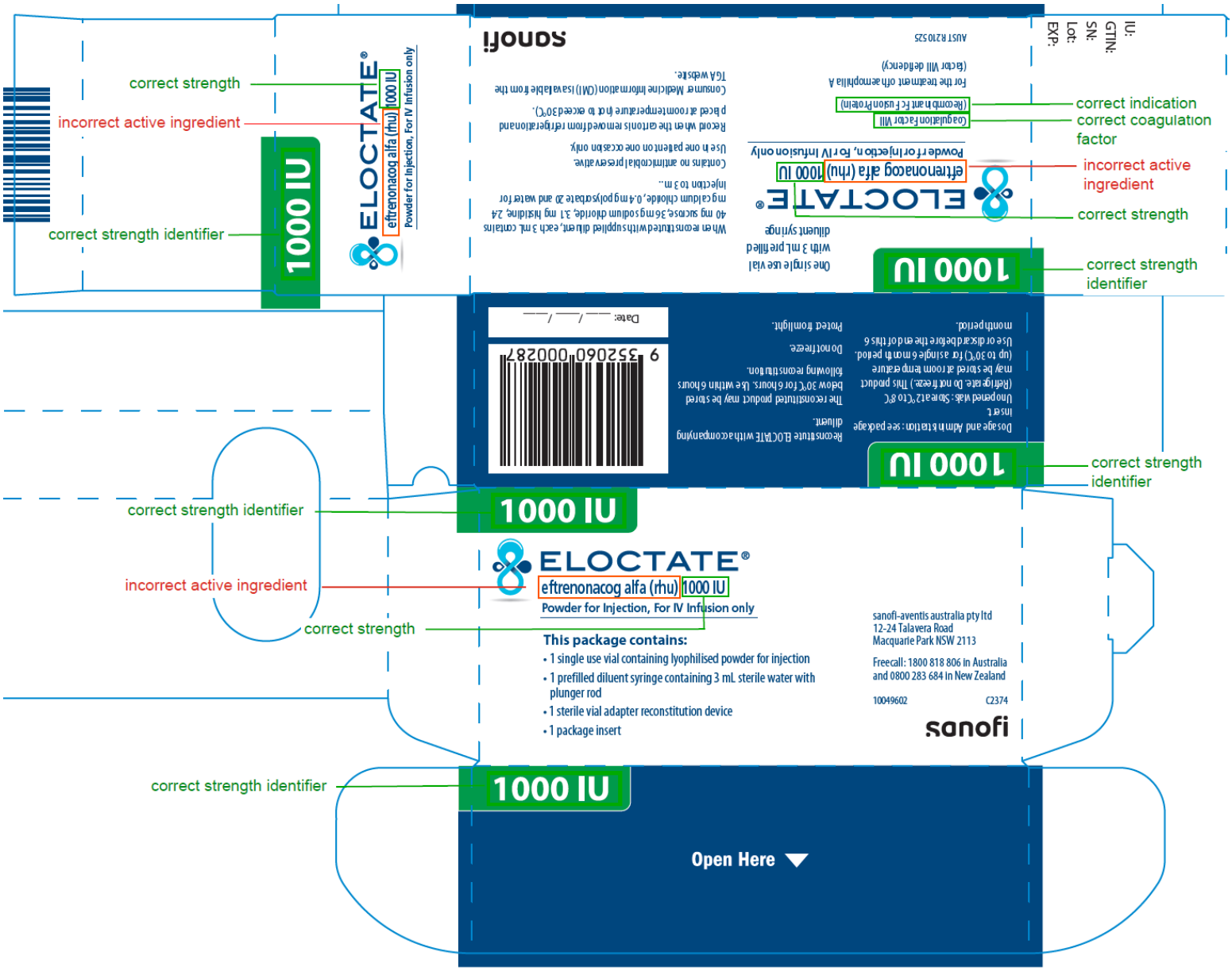

Figure 2: 1000 IU Vial Label

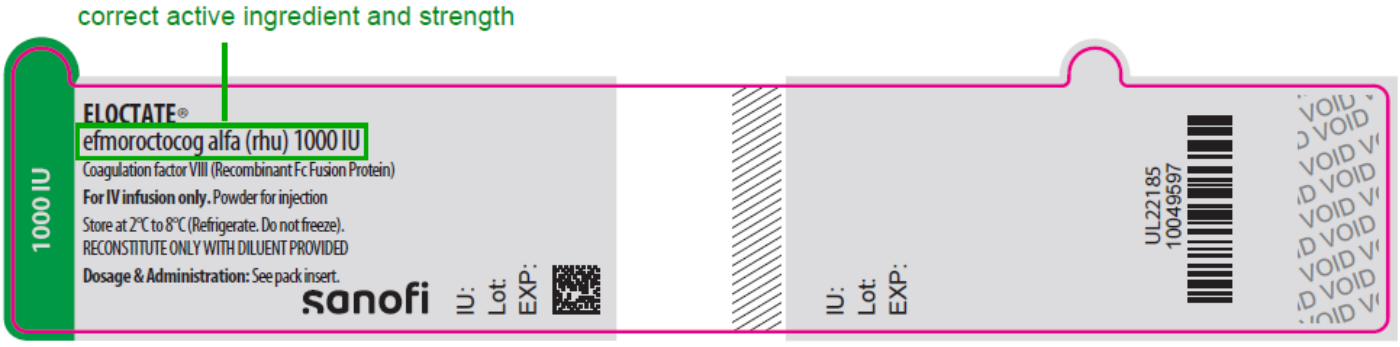

Figure 3: 2000 IU Carton Label

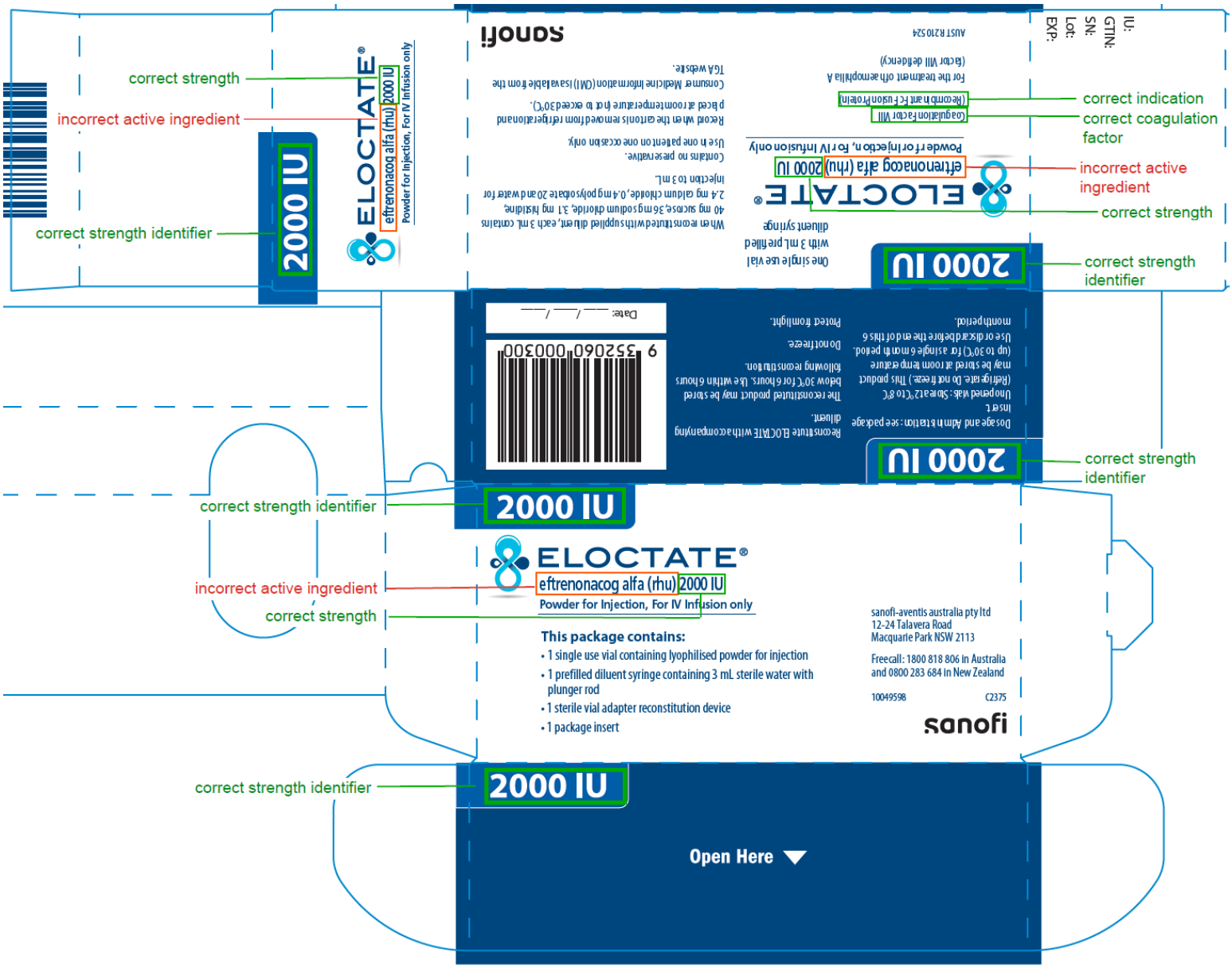

Figure 4: 2000 IU Vial Label

Figure 5: 3000 IU Carton Label

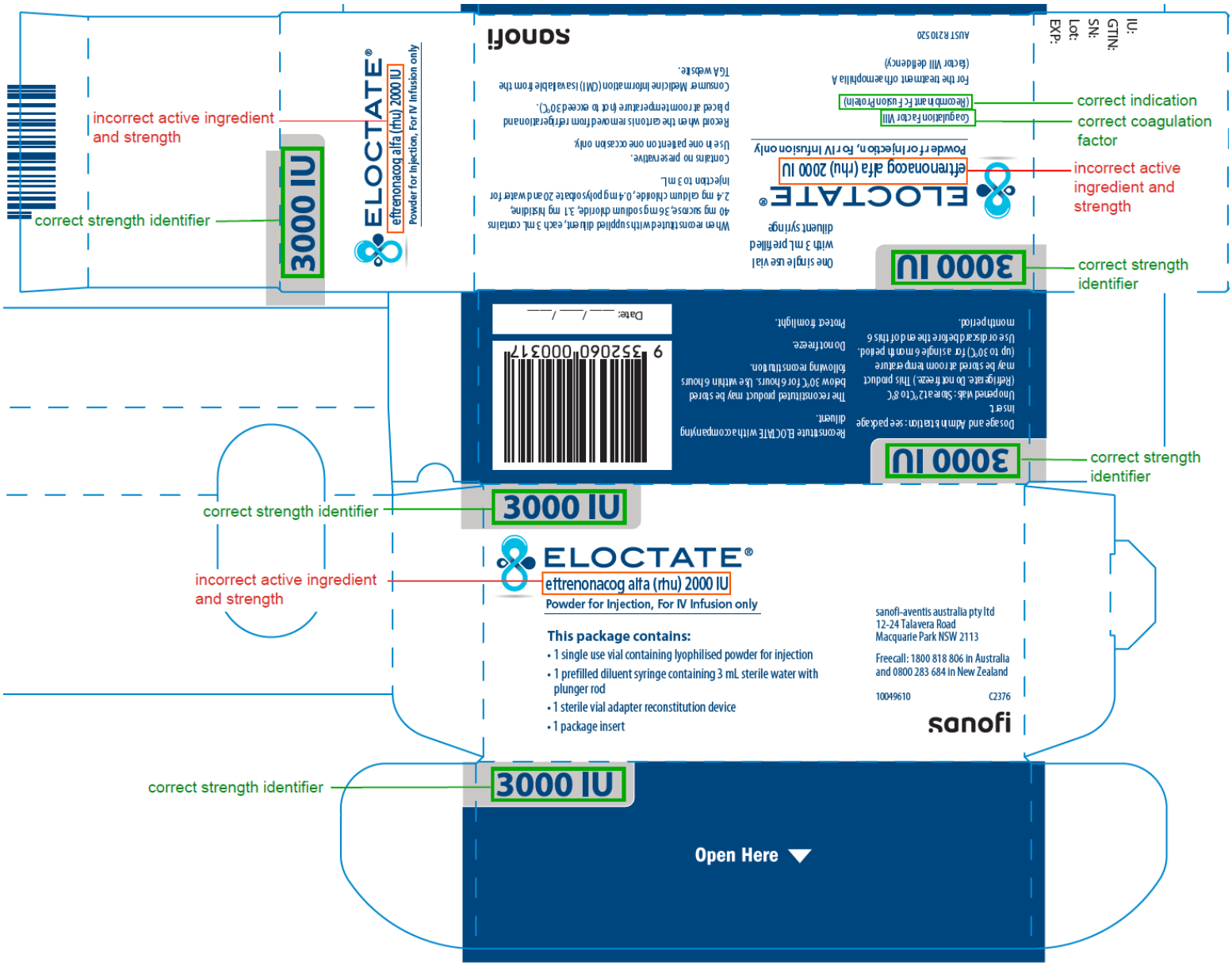

Figure 6: 3000 IU Vial Label