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CSL Behring

PRODUCT ALERT

Medsafe Ref: TT50-8751

Dr Peter Flanagan
National Medical Director
New Zealand Blood Service
71 Great South Road
Epsom
NEW ZEALAND

11 June 2019

Dear Peter,

IMPORTANT ADVICE REGARDING RiaSTAP® (fibrinogen concentrate):

- **Reminder regarding the need to visually inspect reconstituted product prior to administration as stated in the current Data Sheet; and**
- **Notification of a change to the labelled storage conditions.**

CSL Behring writes to advise that during routine stability testing of retained samples of RiaSTAP® (1g, fibrinogen concentrate) CSL Behring's Quality Control Laboratory has noted that following reconstitution, some vials contained small visible white flakes. These white flakes are gel-like, have an overall size of up to 750 µm and consist of fibrinogen and albumin, both of which are components of RiaSTAP®. These same samples passed all other testing parameters.

Following this finding, CSL Behring has conducted a global review of spontaneously reported adverse drug reactions (ADRs), and Pharmaceutical Technical Complaints (PTCs), for RiaSTAP®. This review revealed no evidence of adverse incidents attributable to the abovementioned anomaly. Therefore, this ADR review together with a medical evaluation has confirmed that provided RiaSTAP® is administered in accordance with the dosage and administration instructions in the current Data Sheet, there is no lack of efficacy, and no risks to patient safety.

Nevertheless, CSL Behring requests that you revise and note the following information, which has been agreed following consultation with Medsafe.

CSL Behring

Please be especially reminded of the following section of the current RiaSTAP® Data Sheet leaflet in that:

> **…"After reconstitution, the RiaSTAP® solution should be colourless and clear to slightly opalescent. Inspect visually for particulate matter and discoloration prior to administration. Do not use if the solution is cloudy or contains particulates."**

AND;

In addition, CSLB is requesting users to note a change in storage conditions recently approved by Medsafe:

From old conditions of:

- *Store below 25 °C. Do not freeze. Protect from light. Do not use after the expiry date;*

To the new registered conditions of:

- *Refrigerate between 2 °C to 8 °C. Do not freeze. Protect from light. Do not use after the expiry date.*

Given the new storage requirement is within the old requirement, CSL is requesting users note and implement the new requirement of refrigeration immediately as a precautionary measure and to mitigate against the possibility of wastage.

CSL Behring requests that the NZBS take appropriate steps to remind hospital personnel who are likely to reconstitute and administer RiaSTAP, of the need to inspect RiaSTAP after reconstitution and before infusion. Such steps may include forwarding this Product Alert to the Chairs of Hospital Transfusion Committees within New Zealand.

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Should flakes be observed in the reconstituted solution during the visual inspection step as per the current Data Sheet, please set that product aside and contact our Customer Service Team directly in order to complete a Pharmaceutical Technical Complaint. Please then send this document, together with the sample to:

Contact Information:	CSL Behring Customer Service
Tel (within New Zealand):	0800 841 532
Tel (outside New Zealand):	+613-9246-5231
Fax:	+613-9246-5342
Email:	customerservice@cslbehring.com.au

The current RiaSTAP® Data Sheet can be found on the Medsafe website at **medsafe.govt.nz**. Please also note that this advice relates to all batches of RiaSTAP®.

Yours sincerely,

Dr David Crump
Associate Director, Medical Affairs
CSL Behring