

April 25, 2019

Subject: Change to RiaSTAP® Storage Conditions

Dear Healthcare Professional,

During routine internal stability testing of batches of RiaSTAP® (1g), Fibrinogen Concentrate (Human), our Quality Control Laboratory established that following reconstitution of the product, some of the batches showed evidence of white flakes. These flakes were gel-like in nature, with an overall size of up to 750 µm, and have been observed when the product is stored at higher temperatures. The batches passed all other testing parameters. Detailed investigation confirmed that the flakes consist of fibrinogen and albumin, both of which are components of the product. A further analysis of spontaneously reported, undesired adverse drug reactions (ADRs) and Pharmaceutical Technical Complaints (PTCs) has revealed no evidence of adverse incidents as a result of this development. This analysis, together with a medical evaluation, confirms that there is neither a lack of efficacy, nor a risk to patient safety, provided RiaSTAP is administered in accordance with the instructions for use.

We have reported these observations to the relevant authorities and have agreed to the following change to the storage conditions:

Effective immediately, RiaSTAP should only be stored in a refrigerator at a temperature between +2°C to +8°C.

As noted in the “Reconstitution” section of the Product Monograph:

...“ After reconstitution, the RiaSTAP solution should be colorless 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”.

If you detect flakes, please contact your distributor as per the normal PTC reporting process. Please ensure to provide a sample along with the PTC.

Please note that the product will continue to be made available and that future lots imported to Canada will be provided with updated storage conditions. As an interim solution, until the revised packaging material is implemented, cartons will be delivered with a yellow beacon sticker affixed, informing customers of the revised storage requirements. Also note that the printed expiry date remains unchanged.

We would like to assure you that reliable delivery to our customers remains a priority for CSL Behring and we continue to work intensively with the regulatory authorities to explore any potential, additional mitigation measures. We thank you for your understanding and your continued trust.

Regards,



Rob Bukovcan
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