



---

**ACTION REQUIRED**

Launch of Fibryga® (Fibrinogen Concentrate - Human)  
Customer Letter # 2019-23

---

2019-09-16

Dear Colleagues:

Canadian Blood Services is pleased to announce that FIBRYGA® [Fibrinogen Concentrate – Human], manufactured by Octapharma will be available for distribution following September 16, 2019. Please refer to the attached letter from Octapharma for further details regarding the product.

Based on recent scientific study and stakeholder feedback, Canadian Blood Services anticipates demand for fibrinogen replacement therapy to significantly increase over time. However, confirmed supply of FIBRYGA® is estimated currently to only meet about 50% of total fibrinogen replacement therapy demand.

It is important to note that another licensed fibrinogen concentrate (FC) product (i.e., RiaSTAP® by CSL Behring) is also distributed by Canadian Blood Services. The composition of both FC products is similar and there is no evidence of clinical superiority of one over the other. The major difference between these products is related to product storage – Fibryga® can be stored at room temperature whereas RiaSTAP® needs refrigeration.

Given the current available supply of fibrinogen concentrates, it is necessary to establish an equitable distribution plan to hospitals to meet product demand, ensure security of supply, and minimize wastage of existing fibrinogen replacement products. With these goals in mind, Canadian Blood Services consulted the National Advisory Committee on Blood and Blood Products (NAC) for advice on developing a distribution plan. The following plan has been developed by Canadian Blood Services based on advice from NAC.

**Order Guidelines**

Starting September 16, 2019, Canadian Blood Services will begin to secure a supply of Fibryga® from Octapharma.

For **initial** orders, we recommend for hospitals to:

- assess their current stock of RiaSTAP® and cryoprecipitate and determine an initial Fibryga® order volume based on their best estimates of meeting up to 50% of their total FC inventory, while preventing outdating of current stock.

For **subsequent** orders, we recommend for hospitals to:

- order Fibryga® to meet up to 50% of their total FC demand; the remaining demand of FC should be managed with RiaSTAP®.

Canadian Blood Services will monitor distribution percentages and share data with hospital customers. Hospitals will be able to monitor their own FC percentage transfusion mix using the hospital specific PPP Trend Reports.

If refrigerated storage space is unavailable, hospitals may choose to order Fibryga® only. We ask hospitals to contact their local distribution site to communicate storage limitations and requirement for Fibryga® in greater proportion.

Hospitals may choose to receive up to 100% RiaSTAP® and cryoprecipitate if they prefer to continue with these products only.

**Key Product Highlights:**

- Vial size: Lyophilized 1g/vial
- Diluent 50 mL sterile water for injection, (WFI) will be delivered separately with Fibryga® (not included in product carton)
- Storage Temperature: +2°C to +25°C

Please see the attached Product Profile for additional information.

The following forms have been updated and can be found at:

- [Factor Concentrates and Other Plasma Protein Products Order Form](#)
- [Plasma Protein Products – Customer Table of Information](#)

Please share a copy of this customer letter with healthcare professionals at your hospital who might be interested in this information.

This customer letter can also be viewed at [www.blood.ca](http://www.blood.ca) in the “Hospitals Services” section. If you have questions about this letter, or if you require it in an accessible format, please contact your local hospital liaison specialist.

Sincerely,



Isra Levy, MB BCh, MSc, FRCPC  
Vice President, Medical Affairs and Innovation