

September 18, 2020

**Fibryga® Product Monograph changes: Acquired Fibrinogen Deficiency (AFD) and Infusion rate**

Dear Health Care Professional,

Octapharma would like to inform you about an important change to the product monograph of Fibryga® (Human Fibrinogen Concentrate, (HFC) Octapharma), a double virus inactivated HFC with high purity and fibrinogen activity<sup>1</sup>. On the basis of results from Phase 2 and Phase 3 clinical studies, **Fibryga® has received Health Canada approval for the management of bleeds in Acquired Fibrinogen Deficiency (AFD):**

‘Fibryga® may be used as a complementary therapy during the management of uncontrolled severe bleeding in patients with acquired fibrinogen deficiency in the course of surgical interventions’. Fibryga® is approved for the treatment of acute bleeding episodes and perioperative prophylaxis in adult and pediatric patients with congenital afibrinogenemia and hypofibrinogenemia.

**Dosing and Infusion rate:** In addition to the addition of the AFD indication, important changes have been made to the dosing and infusion rate of Fibryga<sup>2</sup>. **The standard dose of 4 g in AFD can be infused in 10 minutes (maximum rate of 20 mL per minute)**<sup>2</sup>. The ability to rapidly infuse Fibryga® 75% faster can be meaningful in urgent surgical situations. Further, Fibryga® can be reconstituted within approximately 5 minutes using the included Octajet® transfer device.

**Efficacy and Safety in AFD:** The efficacy of Fibryga® in the management of surgical bleed control was demonstrated in **two well controlled studies involving two different types of major surgeries with massive blood loss and transfusion of multiple allogenic blood products**. In both these studies, Fibryga® demonstrated non-inferiority to cryoprecipitate in patients undergoing complex surgeries. In critically ill cardiac surgery patients, the total allogenic blood component units (red blood cells, platelets, and plasma) administered for 24 hours post-surgery were similar to cryoprecipitate. However, Fibryga® demonstrated superiority to cryoprecipitate in non-critical patients in terms of the total allogenic blood component units infused<sup>3</sup>. In both studies, Fibryga® demonstrated a favourable safety and tolerability profile with treatment-emergent adverse events at 28-day being identical in both groups. In the non-cardiac surgical study, all AEs were treatment-emergent and none were assessed as related to study drug administration. Of the 23 AEs six were in the HFC group and 17 were in the cryoprecipitate group. No thromboembolic events were observed in the HFC group. In the cryoprecipitate group, seven patients (30.4%) experienced 7 thromboembolic events (5 patients with pulmonary embolism and 2 patients with DVT)<sup>4</sup>.

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**Room temperature storage and handling:** Fibryga® can be stored at +2 °C to +25 °C for up to 36 months from date of manufacture. The reconstituted solution is stable for up to 24 hours at +25°C<sup>1,2</sup>. The added convenience of storage at room temperature and stability after reconstitution for 24hrs limits product wastage.

**Important Safety Information:** As with all fibrinogen preparations, Fibryga® is contraindicated in patients who have manifested severe immediate hypersensitivity reactions, including anaphylaxis to any product ingredient or component of the container.

For complete prescribing information, refer to the complete [Fibryga® Product Monograph](#). For additional information on Fibryga® or to receive a copy of the above publications, please contact our medical information service by email [medinfo.canada@octapharma.com](mailto:medinfo.canada@octapharma.com) or call 1-888-438-0488.

To request a presentation, or a product demo please contact our Therapeutic Area Leader, Ms. Lynne Bowins at [lynne.bowins@octapharma.com](mailto:lynne.bowins@octapharma.com)

Kind regards,

**Sri Adapa**  
**General Manager**

References:

1. Schulz, P.M. et al. (2018). Biochemical characterization, stability, and pathogen safety of a new fibrinogen concentrate (Fibryga®), *Biologicals: Journal of the International Association of Biological Standardization*, 52, pp. 72–77.
2. [Fibryga® Product Monograph](#), July 16, 2020
3. Callum et al., Effect of Fibrinogen Concentrate vs Cryoprecipitate on Blood Component Transfusion After Cardiac Surgery; *JAMA* 2019;322(20):1966-1976. doi:10.1001/jama.2019.17312 3.
4. Roy et al., Efficacy of fibrinogen concentrate in major abdominal surgery –A prospective, randomized, controlled study in cytoreductive surgery for pseudomyxoma peritonei; *J Thromb Haemost.* 2019; 00:1–12. DOI: 10.1111/jth.14665