

## Fibryna<sup>®</sup> (fibrinogen [human]) – New drug approval

- On June 7, 2017, the [FDA approved](#) Octapharma's [Fibryna \(fibrinogen \[human\]\)](#), for the treatment of acute bleeding episodes in adults and adolescents with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia.
  - Fibryna is not indicated for dysfibrinogenemia.
- [Afibrinogenemia and hypofibrinogenemia](#) are inherited abnormalities resulting from mutations that affect plasma fibrinogen concentration. These conditions are frequently associated with bleeding diathesis, however, may result in a thrombotic event.
  - [Afibrinogenemia and hypofibrinogenemia](#) account for 24% and 38% of all reported cases of fibrinogen disorders, respectively.
- Fibryna contains fibrinogen, a soluble protein that, during the coagulation process, is converted to fibrin, one of the key components of the blood clot. The end product of the coagulation cascade is cross-linked fibrin, which stabilizes the primary platelet plug and achieves secondary hemostasis.
- The safety and efficacy of Fibryna were based on an interim analysis of an open-label, uncontrolled trial involving 13 patients (2 adolescents and 11 adults) with congenital fibrinogen deficiency (afibrinogenemia and hypofibrinogenemia).
  - Of the 22 evaluable bleeding events (BEs), 21 (95%) were rated as good or excellent efficacy. For 1 event, the investigator's assessment was missing.
  - The median number of infusions for the BEs was 1. Two BEs required 2 infusions. None of the BEs required more than 2 infusions.
- Fibryna is contraindicated in individuals who have manifested severe immediate hypersensitivity reactions, including anaphylaxis, to Fibryna or its components.
- Warnings and precautions of Fibryna include hypersensitivity reactions, thrombosis, and transmissible infectious agents.
- The most serious adverse reactions that may be observed with Fibryna use include thromboembolic episodes and anaphylactic type reactions.
- The most common adverse reactions observed in more than one subject in clinical studies with Fibryna (> 5%) were vomiting, weakness and pyrexia.
- The dosing, duration, and frequency of administration for Fibryna should be individualized based on the extent of bleeding, laboratory values, and the clinical condition of the patient.
  - The recommended target fibrinogen plasma level is 100 mg/dL for minor bleeding and 150 mg/dL for major bleeding.
  - The patient's fibrinogen level should be monitored during treatment with Fibryna.
  - Additional infusions of Fibryna should be administered if the plasma fibrinogen level is below the accepted lower limit (80 mg/dL for minor bleeding, 130 mg/dL for major bleeding) of the target level until hemostasis is achieved.

- Octapharma's launch plans for Fibryna are pending. Fibryna will be available as a lyophilized powder in single-use bottles containing approximately 1 gram of fibrinogen concentrate per bottle.



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