Grifols receives US FDA approval for new fibrinogen concentrate, FESILTY™ (fibrinogen, human-chmt)

- ***The new fibrinogen concentrate, FESILTY™ (fibrinogen, human-chmt), is approved in the US for acute bleeding episodes in pediatric and adult patients with congenital fibrinogen deficiency***

- ***FESILTY is expected to be available in the US within the first half of 2026***

- ***The fibrinogen concentrate complements Grifols' bleeding management portfolio, expanding therapeutic options for patients***

Grifols, a global healthcare company and leading producer of plasma-derived medicines, today announced that its fibrinogen concentrate, FESILTY™ (fibrinogen, human-chmt), has been approved by the US Food and Drug Administration for the treatment of acute bleeding episodes in pediatric and adult patients with congenital fibrinogen deficiency (CFD), including hypo- or afibrinogenemia.

Developed and produced by Biotest (a Grifols Group company), FESILTY will be commercialized in the US by Grifols and is expected to be available during the first half of 2026.

CFD is a rare inherited condition present from birth and caused by genetic mutations affecting the production or function of fibrinogen. Produced in the liver, fibrinogen is a plasma protein that is essential for blood clotting and wound healing. Insufficient fibrinogen levels impede the body's ability to effectively control bleeding, particularly during acute bleeding events.[1]

Treatment options for low fibrinogen levels include fresh frozen plasma, cryoprecipitate, or fibrinogen concentrate. Cryoprecipitate and fresh frozen plasma include additional proteins and components that are not necessary for fibrinogen replacement and often require infusions of large volumes to achieve adequate fibrinogen levels.[1]

Grifols' fibrinogen concentrate is a highly purified product with a precisely defined amount of fibrinogen, enabling rapid and predictable restoration of fibrinogen levels – an important benefit in acute bleeding events.[2]

FDA approval was based on evidence from the clinical study "A Prospective, Open-label, Phase I/III Study Investigating Pharmacokinetic Properties of BT524 and Efficacy and Safety of BT524 in the Treatment and Prophylaxis of Bleeding in Patients With Congenital Fibrinogen Deficiency" (NCT02065882).[3]

Please see Important Safety Information on the next page and refer to accompanying full Prescribing Information for FESILTY.

IMPORTANT SAFETY INFORMATION

Indications and Usage

FESILTY (fibrinogen, human-chmt) is a human blood coagulation factor indicated for the treatment of acute bleeding episodes in pediatric and adult patients with congenital fibrinogen deficiency, including hypo- or afibrinogenemia.

Limitations of Use:
FESILTY is not indicated for dysfibrinogenemia.

Contraindications

FESILTY is contraindicated in patients who have severe hypersensitivity reactions, including anaphylaxis, to FESILTY or its components (arginine hydrochloride, polysorbate 80, sodium citrate dihydrate, trehalose dihydrate).

Warnings and Precautions

Hypersensitivity reactions have occurred in patients receiving FESILTY. Should symptoms occur, discontinue FESILTY and administer appropriate treatment.

Thrombotic events have occurred in patients receiving FESILTY. Weigh the benefits of administration versus the risks of thrombosis.

FESILTY is made from pooled human plasma and may carry the risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

Adverse Reactions

The most serious adverse reactions observed with FESILTY were thrombotic events, including portal vein thrombosis, deep vein thrombosis, and pain in extremity with clinically suspected thrombosis. One patient had an episode of epilepsy and died due to extradural hematoma 4 weeks after administration of FESILTY.

In a clinical study, the most common adverse reactions that occurred in >2% of patients receiving FESILTY were pain in extremity, back pain, hypersensitivity reactions, pyrexia, thrombosis, fibrin D dimer increased, headache, and vomiting.

Please see full Prescribing Information for FESILTY.

To report SUSPECTED ADVERSE REACTIONS, contact Grifols Therapeutics LLC at 1-800-520-2807 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

References: 1. May JE, Wolberg AS, Lim MY. Disorders of fibrinogen and fibrinolysis. *Hematol Oncol Clin North Am*. 2021;35(6):1197-1217. **2.** FESILTY™ Prescribing Information. Research Triangle Park, NC: Grifols USA, LLC. 2025**. 3**. National Center for Biotechnology Information. NCT02065882 Pharmacokinetic, Efficacy and Safety of BT524 in Patients with Congenital Fibrinogen Deficiency. https://clinicaltrials.gov/study/NCT02065882. Accessed December 12, 2025.

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