

**News & Events**

FDA NEWS RELEASE

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**FDA approves first long-acting recombinant coagulation Factor IX concentrate for patients with Hemophilia B**

The U.S. Food and Drug Administration today approved Alprolix, Coagulation Factor IX (Recombinant), Fc Fusion Protein, for use in adults and children who have Hemophilia B. Alprolix is the first Hemophilia B treatment designed to require less frequent injections when used to prevent or reduce the frequency of bleeding.

Alprolix is approved to help control and prevent bleeding episodes, manage bleeding during surgical procedures, and prevent or reduce the frequency of bleeding episodes (prophylaxis). Alprolix consists of the Factor IX molecule linked to a protein fragment, Fc, which is found in antibodies. This makes the product last longer in circulation.

“The approval of this product provides another therapeutic option for the treatment and prevention of bleeding in patients with Hemophilia B,” said Karen Midthun, M.D., director of the FDA’s Center for Biologics Evaluation and Research.

Hemophilia B is an inherited sex-linked, blood-clotting disorder, which primarily affects males, and is caused by defects in the Factor IX gene. Hemophilia B affects about 3,300 people in the United States. People with Hemophilia B can experience repeated episodes of potentially serious bleeding, mainly into the joints, which can be destroyed by the bleeding.

The safety and efficacy of Alprolix were evaluated in a multi-center clinical trial that compared each of two prophylactic treatment regimens to on-demand treatment. A total of 123 individuals with severe Hemophilia B, ages 12-71, were followed for up to a year and a half. The studies demonstrated the effectiveness of Alprolix in the prevention and treatment of bleeding episodes and during perioperative management of patients undergoing a surgical procedure. No safety concerns were identified in this trial.

Alprolix received orphan-drug designation for this use by the FDA because it is intended for treatment of a rare disease or condition.

Alprolix is manufactured by Biogen Idec, Inc., Cambridge, Mass.

For more information:

* [Coagulation Factors](http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/ucm127586.htm)

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