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FDA approves rixubis for prophylactic tx in hemophilia B

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(HealthDay)—Rixubis (coagulation factor IX recombinant) has been approved by the U.S. Food and Drug Administration to prevent routine bleeding episodes in people aged 16 and older with hemophilia B, the agency said in a news release.

It's the first recombinant coagulation factor IX to be sanctioned by the FDA. People with hemophilia B, mostly males, have a genetic disorder that leads to a deficiency in factor IX. Affecting some 3,300 people in the United States, the disorder can cause serious bleeding episodes, most commonly affecting the joints, the agency said.

Rixubis is a purified protein supplied as a freeze-dried powder. It is injected twice weekly after being combined with sterilized water.

The treatment was evaluated in clinical studies involving 73 males between the ages of 12 and 65. Those who received the treatment had a 75 percent lower annual bleeding rate than those who had historically received on-demand treatment, the FDA said.

The treatment may lead to life-threatening allergic reactions in some recipients, the agency warned. More common clinical side effects included distorted taste, extremity pain, and atypical blood test results.

Rixubis is produced by Baxter Healthcare, based in Westlake Village, Calif.

More information: More Information