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Adynovate approved for patients with Hemophilia A

Published on November 15, 2015 at 5:59 AM

The U.S. Food and Drug Administration today approved Adynovate, Antihemophilic Factor (Recombinant), PEGylated for use in adults and adolescents, aged 12 years and older, who have Hemophilia A. Adynovate is modified to last longer in the blood and potentially require less frequent injections than unmodified Antihemophilic Factor when used to reduce the frequency of bleeding.

Adynovate is approved for on-demand (as needed) treatment and control of bleeding episodes and to reduce the frequency of bleeding episodes (prophylaxis) in patients with Hemophilia A. Adynovate consists of the full-length Coagulation Factor VIII molecule (historically known as Antihemophilic Factor) linked to other molecules, known as polyethylene glycol (PEGylated). This link makes the product last longer in the patient's blood.

"The approval of Adynovate provides an important therapeutic option for use in the care of patients with Hemophilia A and reduces the frequency of Factor VIII infusions needed to avoid bleeding," said Karen Midthun, M.D., director of the FDA's Center for Biologics Evaluation and Research.

Hemophilia A is an inherited, sex-linked, blood-clotting disorder that primarily affects males, which is caused by defects found in the Factor VIII gene. According to the Centers for Disease Control and Prevention, Hemophilia A affects one in every 5,000 male births in the United States. Patients with hemophilia A may experience repeated episodes of serious bleeding, primarily into the joints, which can be severely damaged as a result.

The safety and efficacy of Adynovate were evaluated in a clinical trial of 137 adults and adolescents aged 12 years and older, which compared the recommended routine prophylactic (preventative) treatment regimen to on-demand therapy. The trial demonstrated that Adynovate was effective in reducing the number of bleeding episodes during routine care. Additionally, Adynovate was effective in treating and controlling bleeding episodes. No safety concerns were identified during the trial.

Adynovate is manufactured by Baxalta US Inc., based in Westlake Village, California.

Source:
http://www.fda.gov
