

Pfizer Receives FDA Approval for Prefilled Dual-Chamber Syringe for Use in the Treatment of Hemophilia A

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New, Innovative Device for the Hemophilia Community

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([BUSINESS WIRE](#))--Pfizer Inc. (NYSE: PFE) announced today that the U.S. Food and Drug Administration (FDA) has granted approval of the use of a Prefilled Dual-Chamber Syringe for administration of XYNTHA® Antihemophilic Factor (Recombinant) Plasma/Albumin-Free to hemophilia A patients. XYNTHA is a recombinant factor VIII product indicated for both the control and prevention of bleeding episodes in patients with hemophilia A (congenital factor VIII deficiency or classic hemophilia) and for surgical prophylaxis in patients with hemophilia A. XYNTHA does not contain von Willebrand factor and, therefore, is not indicated in von Willebrand's disease.

"The approval of the Prefilled Dual-Chamber Syringe is an important milestone for hemophilia patients due to its innovative, convenient reconstitution system that eliminates the transfer step," said Emil Andrusko, vice president, marketing, Specialty Biologics at Pfizer Inc. "Pfizer is committed to the hemophilia community not only through the development of novel reconstitution systems focusing on convenience, such as the XYNTHA Prefilled Dual-Chamber Syringe, but also through early clinical research of other proteins, including Factor Xa and Factor VIIa."

The first Prefilled Dual-Chamber Syringe will provide 3000 IU of XYNTHA, the highest dose, in a low 4 mL volume. Other dosages of XYNTHA will be available in the Prefilled Dual-Chamber Syringe in 2011. The device is used to deliver XYNTHA by intravenous (IV) infusion after reconstitution of a freeze-dried powder with the diluent (0.9% Sodium Chloride). For the first time, both the XYNTHA powder and the diluent are supplied within the Prefilled Dual-Chamber Syringe.

"For the hemophilia A patient who is always on-the-go, any treatment option that can enhance convenience is critical to the management of his health and lifestyle," said Sue Geraghty, RN, MBA, Nurse Coordinator, University of Colorado School of Medicine Hemophilia and Thrombosis Center. "As an all-inclusive, travel-ready kit, the Prefilled Dual-Chamber Syringe offers patients with hemophilia A convenience in reconstituting XYNTHA, potentially saving them both time and effort."

For more information on the Prefilled Dual-Chamber Syringe, visit www.xynta.com.

About XYNTHA

XYNTHA is a recombinant factor VIII product approved by the FDA in February 2008 for both the control and prevention of bleeding episodes in patients with hemophilia A (congenital factor VIII deficiency or classic

hemophilia) and for surgical prophylaxis in patients with hemophilia A. XYNTHA does not contain von Willebrand factor and, therefore, is not indicated in von Willebrand's disease. XYNTHA uses a state-of-the-art manufacturing and purification process that is completely albumin-free, from cell culture to final formulation.

XYNTHA is the only recombinant factor VIII product using a synthetic peptide ligand in lieu of a mouse monoclonal antibody (Mab) in the purification process. It is designed to eliminate the potential risk of murine viral contamination. The purification process also includes a solvent detergent viral inactivation step and a nanofiltration step. These manufacturing and purification processes are designed to reduce the risk of potential viral contamination.

About Hemophilia A

Hemophilia A is an inherited disease that prevents the blood from clotting properly. People with hemophilia A have a deficiency of a blood protein, also called a clotting factor, which is necessary to clot the blood and stop bleeding. Hemophilia A is caused by the absence or deficiency of the protein factor VIII. Most patients with hemophilia A are dependent on factor VIII replacement therapy. According to the National Heart Lung and Blood Institute, about 18,000 people – predominantly males – are affected with hemophilia A in the United States.

Indication for XYNTHA

XYNTHA is indicated for the control and prevention of bleeding episodes in patients with hemophilia A and surgical prophylaxis in patients with hemophilia A. XYNTHA does not contain von Willebrand factor, and, therefore, is not indicated in von Willebrand's disease.

Important Safety Information for XYNTHA

-- Allergic reactions are possible with XYNTHA. Signs of an allergic reaction may include hives, rash with itching, chest tightness, difficulty breathing, faintness, or fast heartbeat. XYNTHA contains trace amounts of hamster protein. You may develop an allergic reaction to these proteins. Tell your doctor if you have had an allergic reaction to hamster protein.

-- Call your doctor right away if bleeding is not controlled after using your factor VIII replacement therapy; this may be a sign of an inhibitor. Inhibitors have been observed in patients receiving factor VIII products, including XYNTHA.

-- The most common adverse reaction in study 1 (safety, efficacy, and pharmacokinetics) is headache (24% of subjects) and in study 2 (surgery) is fever (41% of subjects). Other common side effects of XYNTHA include nausea, vomiting, diarrhea, or weakness.

-- XYNTHA is an injectable medicine administered by intravenous (IV) infusion.

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health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more about our commitments, please visit us at www.pfizer.com.

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