Tretten approved for genetic clotting disorder

December 23 2013, by Scott Roberts, Healthday Reporter

(HealthDay)—Tretten (coagulation factor XIII A-Subunit recombinant) has been approved by the U.S. Food and Drug Administration to treat a very rare blood clotting disorder called congenital Factor XIII A-Subunit deficiency.

People with the genetic disorder do not make enough Factor XIII, a blood component that promotes clotting. Tretten, a human recombinant produced in yeast cells, makes up for this deficiency, which could otherwise be life threatening, the FDA said Monday in a news release.

Tretten was evaluated in a clinical study of 77 people with the disorder. Administered monthly, it was effective in preventing bleeding in 90 percent of recipients. Side effects included headache, extremity pain and pain at the injection site. No study participant developed abnormal clotting, the FDA said.

The product was developed and is produced by Novo Nordisk, based in Denmark.

More information: To learn more about this disorder, visit the National Hemophilia Foundation.