MedicalXpress

Octaplas approved for blood-clotting disorders

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(HealthDay)—Octaplas has been approved by the U.S. Food and Drug Administration to augment insufficient clotting proteins that could otherwise lead to excessive bleeding or excessive clotting.

The product is a sterile, frozen solution made from human plasma. A "solvent detergent process" is applied to minimize the possibility of serious viral transmission, the agency said.

Octaplas should be matched to the recipient's blood type to help avoid transfusion reactions. Each lot is measured for the required presence of clotting factors before the lot is approved for use, the FDA said.

The current version has been used in Europe and elsewhere since 2006, and a prior formulation was first used in 1992. In all, more than 2 million people have been treated with more than 7 million doses outside the United States, the agency said.

Clinical testing of Octaplas focused on people with liver disease, liver transplant and heart surgery, the FDA said. The most common adverse reactions were shortness of breath, chest discomfort, skin itchiness and rash, headache and tingling sensations.

Octaplas is produced by Octapharma, based in Vienna, Austria.

More information: The National Library of Medicine has more about bleeding disorders.