

Kcentra approved to stop severe bleeding in heart patients

April 30 2013

(HealthDay)—Kcentra (prothrombin complex concentrate, human) has been approved by the U.S. Food and Drug Administration to treat severe acute bleeding in adults after administration of the anti-clotting drug warfarin and similar products.

[Blood plasma](#) is the only other product approved for this use, the FDA said in a news release, but plasma requires blood typing and may require thawing. This means Kcentra usually can be administered more quickly than plasma to stop major bleeding.

Warfarin and similar anticoagulants are typically prescribed in cases of atrial fibrillation ([irregular heartbeat](#)) and for people with an artificial heart valve, the FDA said.

Kcentra will carry a boxed label warning that it may increase users' risk of blood clots. Made from the pooled plasma of screened donors, it's processed to minimize recipients' risk of acquiring viruses and other germs, the agency said.

In a study of 216 people who had been receiving [anticoagulation therapy](#) and who developed major bleeding, Kcentra was found to be as effective as plasma in treating the problem, the FDA said.

The drug is produced by the German company CSL Behring.

More information: To learn more about this approval, visit the [FDA](#).

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