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**Generic Name:**

Coagulation Factor X (human)

**Trade Name:**

Coagadex

**Company:**

Bio Products Laboratory Limited

**Notes:**

FDA approved [coagulation Factor X \(human\)](#) for hereditary Factor X (10) deficiency under the trade name Coagadex. Until today's orphan drug approval, no specific coagulation factor replacement therapy was available for patients with hereditary Factor X deficiency.

In healthy individuals, the Factor X protein activates enzymes to help with normal blood clotting in the body. Factor X deficiency is an inherited disorder, affecting men and women equally, in which the blood does not clot as it should. Patients with the disorder are usually treated with fresh-frozen plasma or plasma-derived prothrombin complex concentrates (plasma products containing a combination of vitamin K-dependent proteins) to stop or prevent bleeding. The availability of a purified Factor X concentrate increases treatment options for patients with this rare bleeding disorder.

Coagadex, which is derived from human plasma, is indicated for individuals aged 12 and older with hereditary Factor X deficiency for on-demand treatment and control of bleeding episodes, and for perioperative management of bleeding in patients with mild hereditary Factor X deficiency.

Safety and efficacy of the product were evaluated in a multicenter, nonrandomized study involving 16 participants (208 bleeding episodes) for treatment of spontaneous, traumatic, and heavy menstrual bleeding episodes. Coagadex was demonstrated to be effective in controlling bleeding episodes in participants with moderate to severe hereditary Factor X deficiency.

Coagadex was also evaluated in five participants with mild to severe Factor X deficiency who were undergoing surgery. The five individuals received Coagadex for perioperative management of seven surgical procedures. Coagadex was demonstrated to be effective in controlling blood loss during and after surgery in participants with mild deficiency. No individuals with moderate or severe Factor X deficiency received Coagadex for perioperative management of major surgery, and no safety concerns were identified in either study.

Coagadex was also granted [fast track designation](#) and [priority review](#).

**Medication Monitor Categories:**

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