

Coagadex[®] (coagulation Factor X [human]) – Expanded indication

- On April 14, 2023, the [FDA approved](#) Bio Products Laboratory's [Coagadex \(coagulation Factor X \[human\]\)](#), in adults and children with hereditary Factor X deficiency for perioperative management of bleeding in patients with mild, moderate, **and severe hereditary** Factor X deficiency.
 - Coagadex was previously approved for this indication in patients with mild and moderate Factor X deficiency.
- Coagadex is also approved in adults and children with hereditary Factor X deficiency for:
 - Routine prophylaxis to reduce the frequency of bleeding episodes
 - On-demand treatment and control of bleeding episodes.
- The approval of Coagadex for the expanded indication was based on a post-marketing registry study in 3 patients (aged 21 to 30 years) with severe hereditary Factor X deficiency. Patients received a total of 10 doses of Coagadex for perioperative hemostatic cover.
 - The median initial (pre-surgery) dose was 44.3 IU/kg (mean 40.6; range 28.6 to 48.9). A median of 4 (range 1 to 5) infusions was administered, with median cumulative dose 110.2 IU/kg (range 28.6 to 171.8).
 - All three patients achieved excellent hemostatic efficacy outcomes.
- Refer to the Coagadex for complete dosing and administration recommendations.