## Coagadex ${ }^{\circledR}$ (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 $44.3 \mathrm{IU} / \mathrm{kg}$ (mean 40.6; range 28.6 to 48.9 ). A median of 4 (range 1 to 5 ) infusions was administered, with median cumulative dose $110.2 \mathrm{lU} / \mathrm{kg}$ (range 28.6 to 171.8).
- All three patients achieved excellent hemostatic efficacy outcomes.
- Refer to the Coagadex for complete dosing and administration recommendations.


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