

Coagadex® (coagulation factor X [Human])

When requesting Coagadex, the individual requiring treatment must be diagnosed with one of the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indications

Coagadex is a plasma-derived human blood coagulation factor indicated 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
- Perioperative management of bleeding in patients with mild, moderate, and severe hereditary Factor X deficiency

Coverage Guidelines

- The request is for routine prophylaxis or treatment of bleeding episodes or perioperative management of bleeding in individuals with hereditary Factor X deficiency.

Approval duration (initial): 3 months

Approval duration (renewal): 12 months

Dosing Recommendations

For intravenous use only

For prophylaxis of bleeding episodes:

For less than 12 years of age: the recommended initial dose is 40 IU/kg twice weekly.

For 12 years of age or older: the recommended initial dose is 25 IU/kg twice weekly.

For treatment of bleeding episodes:

For less than 12 years of age: the recommended initial dose is 30 IU/kg, repeat at intervals of 24 hours until the bleed stops.

For 12 years of age or older: the recommended initial dose is 25 IU/kg, repeated at intervals of 24 hours until the bleed stops.

For perioperative management:

For less than 12 years of age: the recommended initial dose is to use a factor of 0.6 to calculate the required dose.

Dose (IU) = body weight (kg) x desired factor X rise (IU/dL or % of normal) x 0.6

For 12 years of age or older: the recommended initial dose is to use a factor of 0.5 to calculate the required dose.

Dose (IU) = body weight (kg) x desired factor X rise (IU/dL or % of normal) x 0.5

For pre-surgery: raise plasma Factor X levels to 70-90 IU/dL.

For post-surgery: maintain plasma Factor X levels at ≥ 50 IU/dL until the patient is no longer at risk of bleeding due to surgery.

References

1. Coagadex prescribing information. Durham, NC; Bio Products Laboratory USA, Inc. April 2023.
2. Coagulation Factor X (human) (Coagadex®). Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. [Updated; April 1, 2024; Accessed August 2, 2024].
3. Menegatti M, Peyvandi F. Treatment of rare factor deficiencies other than hemophilia. *Blood*. 2019;133(5):415-424. doi:10.1182/blood-2018-06-820738.

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