

Prior Authorization DRUG Guidelines

Corifact® (Factor XIII Concentrates)

Effective Date: 1/31/12

Date Developed: 12/9/11 by Albert Reeves MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19

Corifact is an Antihemophilic Agent; Blood Product Derivative. Factor XIII replaces Proteins to stop bleeding.

Pre-Authorization Criteria: prophylaxis against bleeding episodes and management of perioperative surgical bleeding in patients with congenital factor XIII deficiency

Note:

VCHCP requires that Cortifact is prescribed by a Hematologist.

Dosing: ADULTS:

Congenital factor XIII deficiency prophylaxis: I.V.: Initial: 40 units/kg

Maintenance: Dose adjustment based on factor XIII trough levels (target level of 5% to 20% using Berichrom® activity assay) and clinical response; repeat every 4 weeks:

One trough level of <5%: Increase dosage by 5 units/kg

Trough level of 5% to 20%: No dosage change

Two trough levels of >20%: Decrease dosage by 5 units/kg

One trough level of >25%: Decrease dosage by 5 units/kg

Dosing: Pediatric

Refer to adult dosing.

Dosing: Geriatric

Refer to adult dosing.

Dosage Forms

Injection, powder for reconstitution: Corifact®: Exact potency labeled on each vial

[heat treated; supplied with diluent]

Administration

Administer by I.V. infusion at a rate not to exceed 4 mL/minute. Product should

be brought to room temperature prior to infusing. Administer through a separate

infusion line

WARNINGS / PRECAUTIONS

Concerns related to adverse effects:

Antibody formation: The development of factor XIII inhibitory antibodies has been

reported. Factor XIII inhibitory antibodies should be measured when clinical

response (breakthrough bleeding) and/or factor XIII trough levels are suboptimal

after apparent adequate dosing.

Hypersensitivity reactions: Hypersensitivity and anaphylactic reactions have been

reported with use; discontinue immediately if develops.

Thrombotic events: Thromboembolic events have been reported; pregnant

women may be at increased risk due to hypercoagulable state.

DRUG Interactions

There are no known significant interactions.

REFERENCES

- 1. Hsieh L and Nugent D, "Factor XIII Deficiency," *Haemophilia*, 2008, 14(6):1190-200.
- 2. Karimi M, Bereczky Z, Cohan N, et al, "Factor XIII Deficiency," Semin Thromb Hemost, 2009, 35(4):426-38. [PubMed 19598071]

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