

BALFAXAR Is a Non-Activated Human Plasma–Derived 4F-PCC

- BALFAXAR contains coagulation factors II, VII, IX, and X and antithrombotic proteins C and S.¹
- The actual potency of factor IX and potency ranges of factors II, VII, IX, and X, as well as proteins C and S, are stated on the vial label and carton.¹



BALFAXAR Dosage for Reversal of VKA Anticoagulation

Individualize BALFAXAR dosing based on the patient's body weight and predose International Normalized Ratio (INR) value.^{1,a}

Pretreatment INR	2-<4	4-6	>6
Dose^b of BALFAXAR (units^c of factor IX)/kg body weight	25	35	50
Maximum dose^d (units of factor IX)	Not to exceed 2500	Not to exceed 3500	Not to exceed 5000

Administer BALFAXAR¹:

- By intravenous infusion at a rate of 0.12 mL/kg/min (~3 units/kg/min), up to a maximum rate of 8.4 mL/min (~210 units/min)
- Concurrently with vitamin K through a separate infusion line

^aRepeat dosing is not recommended because its safety and effectiveness have not been established.

^bDosing is based on body weight. Dose based on actual potency is stated on the vial, which will vary from 20-32 factor IX units/mL after reconstitution. The actual potency for a 500-unit vial ranges from 400-640 units/vial. The actual potency for a 1000-unit vial ranges from 800-1280 units/vial.

^cUnits refer to International Units.

^dDose is based on body weight up to but not exceeding 100 kg. For patients weighing more than 100 kg, maximum dose should not be exceeded.

Indications and Usage

BALFAXAR (prothrombin complex concentrate, human-lans) is a blood coagulation factor replacement product indicated for the urgent reversal of acquired coagulation factor deficiency induced by Vitamin K antagonist (VKA, e.g., warfarin) therapy in adult patients with need for an urgent surgery/invasive procedure.

WARNING: ARTERIAL AND VENOUS THROMBOEMBOLIC COMPLICATIONS

Please see accompanying full Prescribing Information for additional important information.

Patients being treated with Vitamin K antagonists (VKA) therapy have underlying disease states that predispose them to thromboembolic events. Potential benefits of reversing VKA should be weighed against the potential risks of thromboembolic events, especially in patients with the history of a thromboembolic event. Resumption of anticoagulation should be carefully considered as soon as the risk of thromboembolic events outweighs the risk of acute bleeding. Both fatal and non-fatal arterial and venous thromboembolic complications have been reported with BALFAXAR in clinical trials and post marketing surveillance. Monitor patients receiving BALFAXAR for signs and symptoms of thromboembolic events. BALFAXAR may not be suitable in patients with thromboembolic events in the prior 3 months.

Storage



- Prior to reconstitution, BALFAXAR is stable for up to 36 months at 2°C to 25°C (36°F to 77°F) from the date of manufacture.
- Store the vial in the original package to protect it from light.



- Do not freeze.
- Do not use beyond the expiration date on the vial label and carton.



- Reconstituted solution can be stored for up to 8 hours at room temperature (20°C to 25°C; 68°F to 77°F), provided sterility is maintained.



Based on the results of a usability study, the nextaro® transfer device is preferred over the Mix2Vial® by HCPs^{2,a}

To order BALFAXAR, use NDC Number:

68982-261-01

500 IU Range FIX in 20 mL

68982-261-02

1000 IU Range FIX in 40 mL



Visit balfaxar.com to request more information

Important Safety Information

BALFAXAR is contraindicated in patients with known anaphylactic or severe systemic reactions to BALFAXAR or any of its components. BALFAXAR is also contraindicated in patients with a known allergy to heparin, a history of heparin-induced thrombocytopenia (HIT), and IgA deficient patients with known antibodies against IgA.

In clinical trials, the most frequent ($\geq 3\%$) adverse reactions observed in subjects receiving BALFAXAR were procedural pain, wound complications, asthenia, anemia, dysuria, procedural vomiting, and catheter-site-related reaction.

BALFAXAR is derived from human plasma. The risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent and its variant (vCJD), cannot be completely eliminated.

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^aUser preference was determined from the responses of 16 healthcare providers using an 11-item questionnaire about the usability of the nextaro® and Mix2Vial transfer devices.

Kcentra is a registered trademark of CSL Behring LLC.

Mix2Vial is a registered trademark of West Pharma. Services IL, Ltd., a subsidiary of West Pharmaceutical Services, Inc.

Nextaro is a registered trademark of sfm medical devices GmbH.

References: 1. BALFAXAR, Prothrombin Complex Concentrate (Human) Full Prescribing Information. Paramus, NJ: Octapharma USA Inc. 2. Data on file. Octapharma 2023.