Balfaxar®
Prothrombin Complex Concentrate, Human-lans

BALFAXAR Dosing and Ordering Information

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 per vial of factor X is stated on the carton. The potencies of factors II, VII, IX, and X, as well as proteins C and S, are indicated as ranges.[1]

BALFAXAR Dosage for Reversal of VKA Anticoagulation[1]

Individualize BALFAXAR dosing based on the patient's body weight and predose International Normalized Ratio (INR) value.[1a]

Pretreatment INR	2-<4	4-6	>6
Dose[b] of BALFAXAR (units[c] of factor IX) per 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

[a]Repeat dosing is not recommended because its safety and effectiveness have not been established.

[b]Dosing 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.

[c]Units refer to International Units.

[d]Dose 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.

Administer BALFAXAR[1]:

- 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

Indications

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.

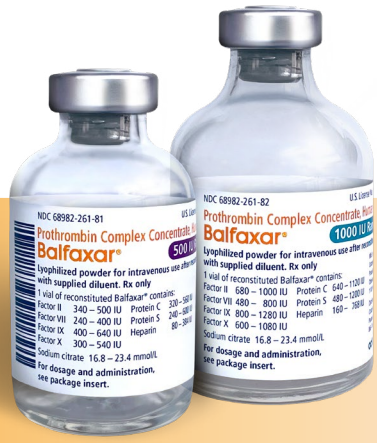
WARNING: ARTERIAL AND VENOUS THROMBOEMBOLIC COMPLICATIONS

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.

Please see Important Safety Information on the back, and accompanying full Prescribing Information, including BOXED WARNING.

Storage[1]

- 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.
- Any unused product or waste material should be disposed of immediately in accordance with local requirements.



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 of the stored product is maintained.

In a survey of healthcare providers, the **nextaro® transfer device** used for BALFAXAR reconstitution was rated **more user friendly** than Mix2Vial used for Kcentra® reconstitution.[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 (≥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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[a]User 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.

Nextaro is a registered trademark of sfm medical devices GmbH.

Kcentra is a registered trademark of CSL Behring LLC.

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

Please see accompanying full Prescribing Information including BOXED WARNING.

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octapharma

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