Balfaxar®
Prothrombin Complex Concentrate, Human-lans

BALFAXAR Reconstitution Guide

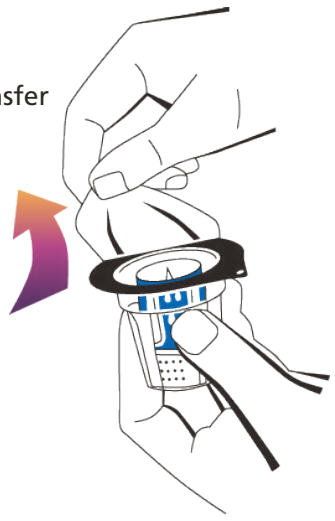
Preparation

- Inspect all components for physical integrity prior to use. Do not use products or components that appear damaged or broken.
- Reconstitute BALFAXAR using aseptic technique.
- Ensure that the lyophilized powder and diluent vials are at room temperature (20°C to 25°C, 68°F to 77°F).
- If the same patient is to receive more than one vial, you may pool the contents of multiple vials, provided that sterility is maintained.

Step 1

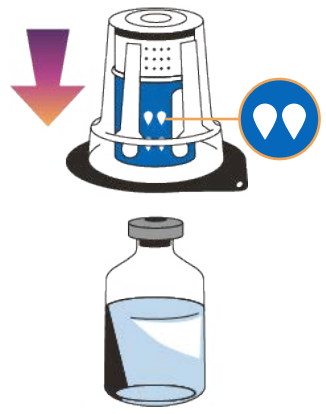
Open the nextaro® transfer device blister package.

The blue color and water drop symbols remind you to place the device on the diluent (or sterile water for injection) vial first.



Step 2

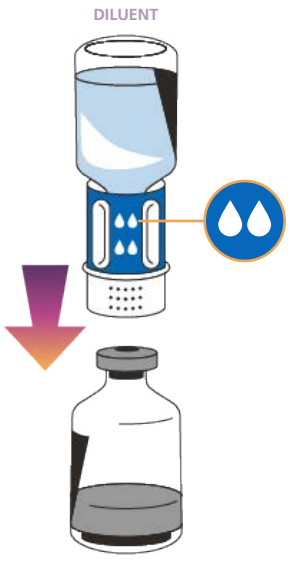
Center the spike and secure the blue part of the transfer device to the diluent vial by pressing straight and firmly down on it until it snaps into place.



Step 3

Carefully remove the blister package from the transfer device. Turn the diluent vial with the attached transfer device upside down.

Center the spike and secure the white part of the transfer device to the lyophilized powder vial by pressing on it until it snaps into place.

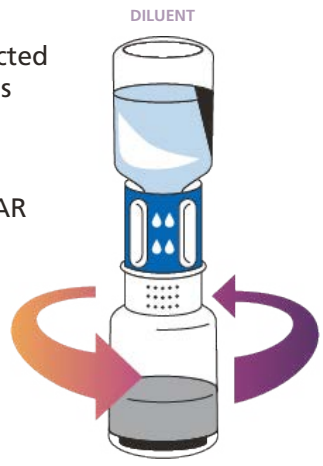


Step 4

Gently **swirl** the connected vials until the product is fully dissolved.

Do not shake.

Reconstituted BALFAXAR will be colorless to slightly blue.

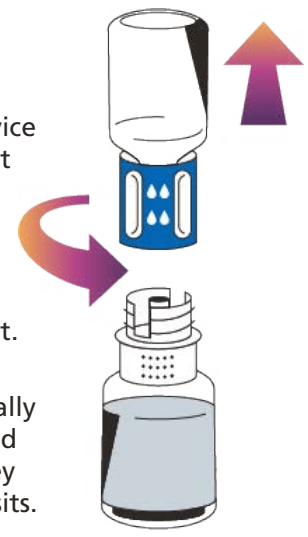


Step 5

Unscrew the transfer device counterclockwise without touching the luer lock connector.

Use a luer slip or luer lock syringe to draw out the reconstituted product.

Reconstituted products should be inspected visually for particulate matter and should not be used if they are cloudy or have deposits.



Scan to view the reconstitution video for more information,
or learn more by visiting balfaxar.com

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 order BALFAXAR or speak with an Octapharma representative*

IMPORTANT SAFETY INFORMATION

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.

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.

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.

Please see accompanying **Full Prescribing Information,** including BOXED WARNING.

octapharma