Biotherapies for Life® CSL Behring

Administering RiaSTAP®: Step-by-Step Guide

RIASTAP™
Fibrinogen Concentrate

Introduction

Contents of the RiaSTAP® Package and Required Components

Mini-Spike® dispensing pin

Syringe filter

Diluent: Single-use Sterile Water for Injection vial (50 mL)

Single-use RiaSTAP® vial containing 1 g human fibrinogen

Antiseptic solution (not provided)

Appropriate administration device (syringe, not provided)

General remarks:

- **Bring the RiaSTAP® vial and diluent to room temperature before administering.**
- RiaSTAP® should be reconstituted with 50 mL Sterile Water for Injection (provided).
- Wash hands or use gloves before reconstituting the product.

Reconstitution

Remove the cap from the RiaSTAP® vial to expose the central portion of the rubber stopper.

Clean the surface of the rubber stopper with an antiseptic solution and allow it to dry.

Transfer the diluent (50 mL Sterile Water for Injection) with an appropriate transfer device or syringe into the RiaSTAP® vial.

Gently swirl the vial to ensure the product is fully dissolved (generally 5 to 10 minutes).
Do not shake the vial; this will cause formation of foam.

Withdrawal

Open the plastic blister containing the Mini-Spike dispensing pin provided with RiaSTAP®.

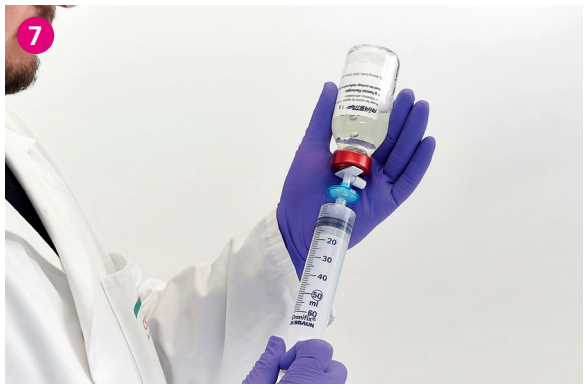
Take the provided dispensing pin and insert it into the stopper of the vial containing the reconstituted product.

After the dispensing pin is inserted, remove the cap. After the cap is removed, do not touch the exposed surface.

Open the blister containing the syringe filter provided with RiaSTAP®.

Screw the syringe onto the filter.

Screw the syringe with the mounted filter onto the dispensing pin.



Draw the reconstituted product into the syringe.

When completed, **remove the filter, dispensing pin and empty vial from the syringe**, dispose of them properly, and proceed with administration as usual.

General remarks:

- Reconstituted product should be administered immediately by a separate injection / infusion line.
- Do not use if the solution is cloudy or contains particulates.
- Any unused product or waste material should be disposed of in accordance with local requirements.

RiaSTAP® is indicated for the treatment of congenital fibrinogen deficiency which comprises congenital afibrinogenemia and hypofibrinogenemia.

Please consult the Product Monograph at cslbehring.ca/products/product-list for important information relating to contraindications, warnings and precautions, adverse reactions, drug interactions, dosing information and conditions of clinical use. The Product Monograph is also available by calling 1-866-773-7721 ext. 2386.

Reference: 1. RiaSTAP® Product Monograph. CSL Behring Canada, Inc. May 27, 2020.

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