RiaSTAP®
Fibrinogen Concentrate (Human), FCH
Fact Sheet

Description

- RiaSTAP® is a pasteurized, preservative free, lyophilized human fibrinogen concentrate. It is derived from human plasma and presented as a white powder for reconstitution with Sterile Water for Injection (provided with the product). RiaSTAP® is to be intravenously (IV) administered for congenital deficiency at a maximum infusion rate of 5 mL per minute.
- Each vial contains 1g human fibrinogen.

Indications

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

Contraindications

- Patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container.

Serious Warnings and Precautions

There is a risk of thrombosis when patients with congenital deficiency are treated with human fibrinogen concentrate, particularly with high dose or repeated dosing.

Adverse Reactions

- The most serious adverse reactions observed in subjects treated with RiaSTAP® during clinical studies or through post-marketing surveillance following RiaSTAP® treatment are allergic-anaphylactic reactions and thromboembolic episodes, including myocardial infarction, pulmonary embolism, deep vein thrombosis and arterial thrombosis.
- The most common adverse reactions that have been reported in clinical studies or through post-marketing surveillance following RiaSTAP® treatment are allergic reactions and generalized reactions such as chills, fever, nausea and vomiting.

Drug Interactions

- No interactions of FCH (Fibrinogen Concentrate Human) with other medicinal products or concurrent illnesses are known.
- No formal drug interaction studies have been conducted with RiaSTAP®, and, to date, no relevant interactions are known.

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RiaSTAP® Fibrinogen Concentrate

Recommended Dose and Dose Adjustment for Congenital Deficiency

- The dose of RiaSTAP® to be administered and the frequency of administration are based on the extent of bleeding, laboratory values and the clinical condition of the individual patient.
- Determination of the patient's fibrinogen level is recommended before and during the treatment with RiaSTAP®.
    - If the patient's fibrinogen level is not known, the recommended dose is an IV administration of 70 mg/kg of body weight (b.w.).
    - Target level (1 g/L) for minor events (e.g., epistaxis, intramuscular bleeding or menorrhagia) should be maintained for 3 days.
    - Target level (1.5 g/L) for major events (e.g., head trauma or intracranial hemorrhage) should be maintained for 7 days.

$$\textbf{Dose of fibrinogen (mg/kg b.w.)} = \frac{\textbf{[Target level (g/L) - Measured level (g/L)]}}{\textbf{0.017 (g/L per mg/kg b.w.)}}$$

Method of Administration for Congenital Deficiency

- For intravenous use only and should be reconstituted with 50 mL of Sterile Water for Injection prior to use.
- After reconstitution, the RiaSTAP® solution should be colourless and clear to slightly opalescent. Inspect visually for particulate matter and discolouration prior to administration. Do not use if the solution is cloudy or contains particulates.
- A Mini-Spike® dispensing pin and syringe filter are provided and should be used to filter the reconstituted product prior to administration.
- Administer at room temperature by slow intravenous injection, at a rate not exceeding 5 mL per minute (approximately 100 mg/minute).
- RiaSTAP® should not be mixed with other medicinal products or intravenous admixtures and should be administered through a separate injection site. Use aseptic technique when administering RiaSTAP®.
- RiaSTAP® should be administered under the supervision of a physician.

Storage and Stability

- RiaSTAP® should be stored in a refrigerator between 2°C to 8°C.
- RiaSTAP® is stable for the period indicated by the expiration date on the outer carton and vial label.
- Keep RiaSTAP® in its original carton until ready to use. Do not freeze. Protect from light. The shelf life of RiaSTAP® is 60 months.

Please consult the Product Monograph at cslbehring.ca/products/product-list for 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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