**XXXXX Hospital/Health Centre**

**BLOOD COMPONENT OR PRODUCT ADMINISTRATION GUIDELINES/MONOGRAPHS**

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| **Blood Comp/Product Name:** | **Approved By:**  **Date Approved:**  **Effective Date:** | **Page 1 of 3**  **Document #: xxxx**  **Version #: v2** |
| Fibrinogen Concentrate (Human)  Other names: RiaSTAP |

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| **Classification/**  **Indications** | RiaSTAP is a pasteurized, lyophilized, preservative free fibrinogen concentrate derived from human plasma. The product is reconstituted with sterile water and also contains human albumin, L-arginine hydrochloride, sodium chloride and sodium citrate  It is used for the treatment of congenital fibrinogen deficiency in:   * Afibrinogenemia * Hypofibrinogenemia |
| **Precautions/ Contraindications** | There is a risk of thrombosis when patients are treated with this product, particularly with high and/or repeated dosing. Use with caution in pregnant and nursing women, neonates and pediatrics and the elderly due to insufficient safety studies. There are no known drug interactions.  Do not use:   * In patients who are hypersensitive to the drug or any of the components in the formulation |
| **Supplied** | Supplied in single dose vials of 1 g fibrinogen with 50 mL of sterile water for reconstitution. This unconstituted product is stored at 2-25°C (refrigerator or room temperature) and has a shelf life of 60 months. Do not freeze or expose to the light. |
| **Dosage** | Once reconstituted, the injection will contain approximately 20 mg/mL.  Dosage is dependent on the patient’s fibrinogen level and clinical condition.  Suggested target is 1 g/L of fibrinogen for minor bleeding and 1.5 g/L for major bleeding. Maintain levels until hemostasis is reached.  INITIAL DOSE: in normal weight adults: 3,000 – 4,000 mg or 70 mg/kg  SUBSEQUENT DOSES if fibrinogen level is known: Dose in mg =  [ (Target level g/L – Measured level g/L ) ÷ 0.017 ] x Patient weigh (kg). Can round to the nearest thousand. |
| **Reconstitution/**  **Stability** | Reconstitute as follows:  1. Bring vials to room temperature before reconstituting  2. Reconstitute with the 50 mL of sterile water diluent provided  3. Remove cap from lyophilized product to expose central portion of stopper  4. Clean stopper surface with antiseptic and allow to dry |

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| **Reconstitution/**  **Stability** | 5. Using a transfer device or syringe, transfer the full 50 mL of diluent (sterile water) into the product vial  6. Gently swirl the product vial until the product is fully dissolved. Usually takes 5-10 minutes. Do not shake the vial as it creates foaming  Inspect product. It should appear clear and colourless to slightly opalescent. Discard if particulate matter is present or if it is discoloured.  Store reconstituted product at room temperature for a maximum of 8 hours. Do not refrigerate or freeze. Product should be administered as soon as possible. |
| **Compatibilities/**  **Incompatibilities** | Only reconstitute with the sterilized water diluent provided.  Do not mix or infuse with any other product, solution or drug.  The sodium content may exceed 200 mg per treatment, so use with caution in patients with sodium restrictions. |
| **Administration/**  **Identification** | Positively identify and/or confirm, before product administration:   * The recipient * The product * The order and dose * Informed consent has been obtained   ABO and Rh is not a concern with this product. No transfusion medicine testing (e.g. group and screen, crossmatch) is required. |
| **Administration-method** | Product should be at room temperature.  Use a separate injection site and do not mix with any other substances.  Administer product intravenously. Do not exceed 5 mL per minute (100 mg/minute).  Discard any partially used product.  Observe and monitor at least:   * Before the infusion * During infusion * At the end of infusion * During any reactions to the product |
| **Adverse Events**   * Stop the infusion * Notify physician * Treat symptoms * Notify TM laboratory * Follow transfusion reaction policy | Although rare with this product, the most common reactions are allergic ones (rash) and generalized reactions such as chills, fever, nausea and vomiting.  More serious, but rare events include:   * Anaphylaxis * Thrombotic events: myocardial infarction, pulmonary embolism, deep vein thrombosis and arterial thrombosis |