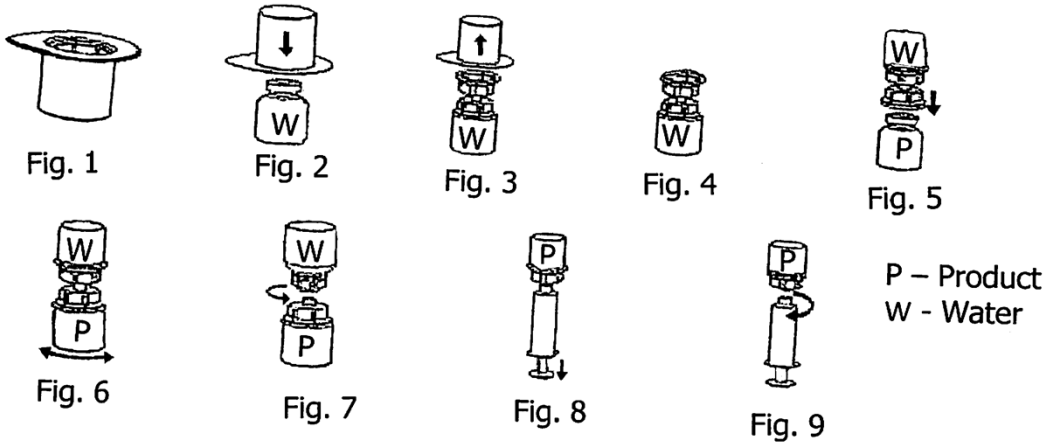
Other Names	• Factor XIII
Description	• Corifact is derived from human plasma, presented as a white lyophilized powder to reconstitute with Sterile Water for injection

Special Approvals/Authorizations	• An independent 2 person check is required for all doses. Nurses from the Manitoba Bleeding Disorder Program are exempt from the independent 2 person check.
	• A nurse may administer a dose that provides:
	  ○ Up to 200 units greater than the prescribed dose; or
	  ○ No more than 100 units less than the prescribed dose without receiving a new medication order.
	• Patients accustomed to self-administering Factor VIII may continue to do so on the written order of a hematologist or designate.

Classification	**Special Populations:** **Pediatrics (less than 12 years of age):** There are no apparent differences in the safety profile in children as compared to adults. **Geriatrics (greater than 65 years of age):** The safety and efficacy of Corifact in the geriatric population have not been established due to insufficient number of subjects. **Pregnant and nursing women:** Limited data on the clinical use of Corifact in pregnancy did not show any negative effect on the course of gestation and the peri or postnatal development. Corifact should be used during pregnancy only if clearly indicated. It is now known whether Corifact is excreted in human milk. However, based on its large molecular size excretion into milk is unlikely and due to its proteinaceous character, absorption of intact molecules by the infant is also unlikely. Therefore, the use of Corifact may be considered during breastfeeding, if necessary.
Indications	• Indicated for routine prophylactic treatment and peri-operative management of surgical bleeding in adult and pediatric patients with congenital Factor XIII deficiency.
Contraindications	• Contraindicated in individuals with known anaphylactic or severe systemic reactions to human plasma-derived products or to any components in Corifact.
Supplied	Vial size is 250 international units or 1250 international units.
Dosage	**Recommended dose and dose adjustment for routine prophylaxis is 40 international units/kg every 28 days.**
Reconstitution/Stability	**Reconstitution:** **1.** Bring the Corifact vial powder and diluent to room temperature. **2.** Place the Corifact vial, diluent vial and Mix2Vial transfer set on a flat surface. **3.** Remove Corifact vial and diluent vial flip caps and wipe the stoppers with an antiseptic. Allow to dry prior to opening the Mix2Vial transfer set package. **4.** Open the Mix2Vial transfer set package by peeling away the lid (Fig. 1). To maintain sterility, leave the Mix2Vial transfer set in its clear outer package. **5.** Place the diluent vial on an even flat surface and hold the vial tightly. Grip the Mix2Vial transfer set keeping it in the clear package and push the plastic spike of the blue end of the Mix2Vial transfer set firmly through the center of the diluent vial stopper (Fig. 2). **6.** While holding the diluent vial, carefully remove the outer package from the Mix2Vial transfer set. Make sure to pull off only the clear package, not the Mix2Vial transfer set (Fig. 3). **7.** Place the Corfiact vial on an even flat surface and hold the vial tight (Fig. 4). Invert the diluent vial with the Mix2Vial transfer set attached to it and push the plastic spike of the clear end of the Mix2Vial firmly through the center of the stopper of the Corifact vial (Fig. 5). The diluent will transfer into the Corifact vial automatically. **8.** With the diluent and Corifact vial still attached to the Mix2Vial transfer set, gently swirl the Corifact vial to ensure that the Corifact is fully dissolved (Fig. 6). Do not shake the vial.

	9. With one hand, grip the clear end of the Mix2Vial transfer set and with the other hand grip the blue end of the Mix2Vial transfer set, and unscrew counterclockwise the set into two pieces (Fig. 7). **10.** Draw air into an empty, sterile syringe. With the Corifact vial upright screw the syringe to the Mix2Vial transfer set. Inject air into the Corifact vial. While keeping the syringe plunger pressed, invert the Corifact vial and draw the solution into the syringe by pulling the plunger back slowly (Fig. 8). **11.** Once the solution has been transferred into the syringe, firmly grip the barrel of the syringe (keeping the plunger facing down) and unscrew the syringe counterclockwise from the Mix2Vial transfer set (Fig. 9). **12.** Attach the syringe to an infusion set or another suitable administration set.  Fig. 1 Fig. 2 Fig. 3 Fig. 4 Fig. 5 Fig. 6 Fig. 7 Fig. 8 Fig. 9 **Stability:** • Stable at 2-8 ºC until the expiry date indicated on the label. • Do not freeze. • Protect from light. • Do NOT mix with other medicinal products. • The reconstituted product must be used within 3 hours.
Compatibilities/ Incompatibilities	• Must not be mixed with other medicinal products.
Administration, Identification and ABO Compatibility	Refer to **Manitoba Best Practice Guidelines** • section 2.2 Standards- Identification and Administration • ABO Compatibility not applicable
Administration, Method	Maximum Concentration: • Not applicable Maximum Rate: • Administer at a rate of 4 mL per minute.
Adverse Events	• The most common adverse drug reactions reported were joint inflammation, hypersensitivity, rash, pruritus, erythema, hematoma, arthalgia, headache, elevated thrombin-antithrombin levels and increased blood lactate dehydrogenase. **ADVERSE REACTIONS REPORTED:** HYPERSENSITIVITY Rash, pruritus, erythema, urticaria, tightness of chest, wheezing and hypotension CARDIOVASCULAR Thromboembolic complication, alteration in blood pressure ENDOCRINE AND METABOLISM Corifact contains 124.4 to 195.4 mg sodium per dose (40 IU/kg). This should be taken into consideration in patients on a controlled sodium diet. GASTROINTESTINAL

	Nausea IMMUNE Inhibitory antibodies against FXIII have been detected in patients receiving Corifact , fever, chills, dyspnea GENERAL DISORDERS Pyrexia
References:	Product Monograph – Date of Approval: December 8, 2015
Reviewed By:	Dr. Donald Houston Dr. Jayson Stoffman