



**Prior Authorization Approval Criteria**  
*Department of Pharmacy Services*

**Generic Name:** Factor IX Complex (Human)

**Brand Name:** Bebulin® VH, Profilnine® SD, Proplex® T, Konyne® 80

**Medication Class:** Antihemophilic Agent

**FDA Approved Uses:**

- Prevention and control bleeding in patients with factor IX deficiency, also known as hemophilia B or Christmas disease
- Emergency correction of the coagulopathy of warfarin excess in critical situations
- In addition, Proplex® T and Konyne® 80 are also used for prevention and control of bleeding in hemophilia A patients with inhibitors to factor VIII
- Proplex® T may also be used for prevention and control of bleeding in patients with factor VII deficiency

**Available Dosage Forms:** Powder for reconstitution for IV administration only

**Usual Dose:** must be individualized depending on the severity of factor IX deficiency

- Dosage based on desired factor IX increased (%):  
Int. units factor IX = (Body Weight) x (desired factor IX increased %) x 1.0 IU/kg (x 1.2 IU/kg for Bebulin® VH)  
Recommended dose:
  - Minor to moderate hemorrhage: 15-25% IV once, repeated in 24 hrs if needed
  - Major hemorrhage and surgery: 30-50% IV q18-30 hrs up to 10 days
- Factor VIII inhibitor patients: 75 units/kg/dose; may repeated q 6-12 hrs
- Anticoagulant overdose: 15 units/kg

**Duration of Therapy:** Usually 1 to 3 days

**Criteria for Use:** *(bullet points below are all inclusive unless otherwise noted)*

- Patients with factor IX or VII deficiency experiencing a bleeding episode
- Hemophilia A patients with inhibitors to factor VIII

**Criteria for Continuation of Therapy:** may be used until healing is achieved

**Cautions:**

- Products may potentially contain infectious agents
- Identification of the clotting factor deficiency (factor IX, VII or VIII with inhibitor) prior to starting therapy
- Possibility of hypersensitivity reactions
- Cautions to patients with liver disease, thrombosis or DIC
- Cautions to post-operative patients or patient patients undergoing surgery
- Pregnancy and lactation



**Monitoring:**

- Signs or symptoms of thrombosis, including RR, BP, pulse, respiratory distress, chest pain and cough
- PTT, PT
- Levels of factors being replaced, such as IX, VII
- Levels of factors II, X

**Contraindications:**

- Hypersensitivity to any component of formulation
- Patients with DIC (Proplex® T)

**Not Approved if:**

- Patients have immune tolerance induction
- Being used for control of bleeding episodes in patients with mild Factor IX deficiency in whom fresh frozen plasma is effective

**Special Considerations:** for prophylaxis dose, 2 to 3 times a week may be sufficiency

P&T Approval: \_\_\_\_\_ Date: \_\_\_\_\_