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 overdosage: 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: ________________