factor IX (human)

AlphaNine SD, BenFix, Mononine, Profilnine SD, Proplex T, Bebulin VH

Classification
Therapeutic: hemostatic agents
Pharmacologic: blood products, clotting factor replacements

Pregnancy Category C

Indications

Action
Factor IX complex preparations (Bebulin VH, Profilnine SD, Proplex T) contain blood coagulation factors II, VII, IX, and X. Purified protein preparations (AlphaNine SD, BenFix, Mononine) contain factor IX activity only. BenFix is made via recombinant DNA technology.

Therapeutic Effects: Replacement of deficient factor IX in hemophilia B. Restoration of hemostasis.

Pharmacokinetics
Absorption: Administered IV only, resulting in complete bioavailability.
Distribution: Unknown.
Metabolism and Excretion: Rapidly cleared from plasma by utilization in clotting process.
Half-life: Factor IX — 24–32 hr; factor VII — 3–6 hr.

TIME/ACTION PROFILE (hemostasis)

<table>
<thead>
<tr>
<th>ROUTE</th>
<th>ONSET</th>
<th>PEAK</th>
<th>DURATION</th>
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</thead>
<tbody>
<tr>
<td>IV</td>
<td>immediate</td>
<td>10–30 min</td>
<td>1–2 days</td>
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Contraindications/Precautions
Contraindicated in: Factor VII deficiency (except Proplex T); Intravascular coagulation or fibrinolysis associated with liver disease; Allergy to mouse protein (Mononine).

Use Cautiously in: Postoperative period (increased risk of thrombosis).

Adverse Reactions/Side Effects

Interactions
Drug-Drug: Use with aminocaproic acid may ↑ risk of thrombosis.

Route/Dosage

The following general formula may be used: Human-derived products — Dose (units) = body weight (kg) × 0.1 unit/kg × desired factor IX increase (% of normal). Recombinant DNA product — Dose (units) = body weight (kg) × 1.2 units/kg × desired factor IX increase (% of normal).

Hemophilia B

IV (Adults and Children): Major bleeding — 50–100% activity q 12–24 hr for 7–10 days; moderate bleeding — 25–50% activity q 12–24 hr until bleeding stops and healing begins (1–7 days); minor bleeding — 20–30% activity q 12–24 hr for 1–2 days.

Factor VII Deficiency (Proplex T only)

IV (Adults and Children): 75 units/kg.

NURSING IMPLICATIONS

Assessment

- Monitor BP, pulse, and respiration frequently.
- Obtain history of current trauma; estimate amount of blood loss.
- Monitor for new or increased bleeding every 15–30 min. Hemorrhage and apply to affected areas.
- If hypersensitivity reaction (fever, chills, urticaria, headache, urticaria, changes in BP or pulse, nausea and vomiting, laryngeal) occurs, slow infusion and notify physician.

- Pyrogenic reactions (fever, chills) may also occur and are more common with high doses.

- Lab Test Considerations: Monitor complete blood counts; activated partial thromboplastin time (aPTT); plasma fibrinogen; platelet count; PT, factor IX

- Stop infusion immediately if signs of anaphylaxis occur.
plasma concentrations) before, during, and after therapy to assess effectiveness of therapy.

Potential Nursing Diagnoses
- Ineffective tissue perfusion (Indications)
- Risk for injury (Indications)
- Deficient knowledge, related to medication regimen (Patient/Family Teaching)

Implementation
- Dose varies with degree of clotting factor deficit, desired level of clotting factors, and weight.
- Obtain type and crossmatch of blood in case a transfusion is necessary.
- Hepatitis B vaccine may be given prior to therapy to prevent hepatitis.
- Inform all personnel of patient’s bleeding tendency, to prevent further trauma. Apply pressure at all venipuncture sites for at least 5 min; avoid all IM injections.

IV Administration
- Direct IV: Refrigerate concentrate until just prior to reconstitution.
  - Diluent: Diluent (sterile water for injection) is room temperature before reconstituting. Use plastic syringe for preparation and administration. Use the filter needle provided by the manufacturer as an air vent to the vial when reconstituting. After adding diluent, rotate vial gently until contents are completely dissolved. Reconstituted solution generally requires 5–10 min for factor IX complex and 1–5 min for coagulation factor IX. Do not refrigerate after reconstitution. Begin administration within 3 hr.
  - Do not refrigerate after reconstitution.

- Discard partially used vials.
- Additive Incompatibility: Reconstitute only with diluent provided. Administer through a separate line. Do not mix with other solutions or medications.

Patient/Family Teaching
- Instruct patient to notify health care professional immediately if bleeding recurs.
- Advise patient to avoid products containing aspirin or NSAIDs, because they may further impair clotting.
- Review with patient methods of preventing bleeding (use soft toothbrush, avoid DM and subcutaneous injections, avoid potential traumatic activities).
- Advise patient that the risk of hepatitis or AIDS transmission may be decreased by use of heat-treated preparations. Current screening programs and vaccination with hepatitis B vaccine should help decrease the risk.
- Reinforce need for patient with hemophilia to receive close medical supervision.

Evaluation/Desired Outcomes
- Prevention of spontaneous bleeding or control of bleeding in patients with factor IX deficiency (hemophilia B, Christmas disease), factor VIII inhibitors, factor VII deficiency, or anticoagulant overdose.

Why was this drug prescribed for your patient?
- Caution patient to avoid products containing aspirin or NSAIDs, because they may further impair clotting.
- Review with patient methods of preventing bleeding (use soft toothbrush, avoid DM and subcutaneous injections, avoid potentially traumatic activities).
- Advise patient that the risk of hepatitis or AIDS transmission may be decreased by use of heat-treated preparations. Current screening programs and vaccination with hepatitis B vaccine should help decrease the risk.
- Reinforce need for patient with hemophilia to receive close medical supervision.