

Factor IX (Human)

Brand names AlphaNine SD, BeneFIX, Mononine

Medication error potential Factor IX may be confused with Factor IX complex.⁽¹⁾

Contraindications and warnings **Contraindications:** Hypersensitivity or intolerance to any component in the product.⁽²⁻⁴⁾
Product-specific contraindications:

BeneFIX: Known hypersensitivity to hamster protein.⁽³⁾

Mononine: Known hypersensitivity to mouse protein.⁽⁴⁾

Other warnings: All products contain polysorbate 80, which may cause allergic reactions in susceptible individuals, especially neonates.⁽²⁻⁴⁾

AlphaNine SD and Mononine are prepared from human pooled plasma and may carry a risk for transmission of infectious agents, despite viral attenuation processes.^(2,3,5,7) Hepatitis A and B vaccination are recommended in all hemophilia patients.⁽⁷⁾

Serious and potentially fatal thrombosis or disseminated intravascular coagulation may occur in patients with hepatic impairment and in patients undergoing surgery. Use with caution in patients with liver disease, neonates, postoperatively, or patients with signs of fibrinolysis. Monitor all patients closely for thromboembolic complications.^(2-4,6)

Hypersensitivity and anaphylactic reactions have been reported with all Factor IX products, usually in association with the development of Factor IX inhibitors. Delayed reactions in previously untreated patients may occur. Patients should be closely monitored between the 10th and 20th exposure day.⁽²⁻⁴⁾

Nephrotic syndrome has been reported following immune tolerance induction with Factor IX products in Hemophilia B patients with Factor IX inhibitors and a history of severe allergic reactions to Factor IX.⁽²⁻⁴⁾

Infusion-related cautions All products have been associated with reactions such as urticaria, fever, chills, nausea, vomiting, headache, somnolence, lethargy, flushing, or tingling. Reduce infusion rate or use a different lot.⁽²⁻⁴⁾

Dosage Individualize dosage based on severity of Factor IX deficiency, extent, and location of bleeding and the patient's clinical status.⁽⁵⁾

Formula for international units required to raise blood level %

AlphaNine SD: Number of Factor IX international units required = body weight (kg) × desired Factor IX level increase (% normal) × 1 international unit/kg⁽²⁾

BeneFIX

<15 years: Number of Factor IX international units required = body weight (kg) × desired Factor IX level increase (% normal) × 1.4 international units/kg⁽³⁾

≥15 years: Number of Factor IX international units required = body weight (kg) × desired Factor IX level increase (% normal) × 1.3 international units/kg⁽³⁾

Mononine: Number of Factor IX international units required = body weight (kg) × desired Factor IX level increase (% normal) × 1 international unit/kg⁽⁴⁾

Hemorrhages

Minor hemorrhage (bruises, cuts or scrapes, uncomplicated joint hemorrhage)

AlphaNine SD: Raise Factor IX levels to 20% to 30% of normal. Typical dose: 20–30 international units Factor IX/kg q 12 hr until hemorrhage stops and healing has been achieved (about 1–2 days).⁽²⁾



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BeneFIX: Raise Factor IX level to 20% to 30% of normal. Dose q 12–24 hr for 1–2 days.⁽³⁾

Mononine: Raise Factor IX level to 15% to 25% of normal. Initial loading dose up to 20–30 international units/kg administered once and repeated in 24 hours if needed.⁽⁴⁾

Moderate hemorrhage (nose bleeds, mouth and gum bleeds, dental extractions, hematuria)

AlphaNine SD: Raise Factor IX levels to 25% to 50% of normal. Typical dose: 25–50 international units Factor IX/kg q 12 hr until healing has been achieved, usually 2–7 days.⁽²⁾

BeneFIX: Raise Factor IX level to 25% to 50% of normal. Dose q 12–24 hr until bleeding stops and healing begins, usually 2–7 days.⁽³⁾

Major hemorrhage (joint and muscle hemorrhages, major trauma, hematuria, intracranial and intraperitoneal bleeding)

AlphaNine SD: Raise Factor IX level to 50% for at least 3–5 days. Typical dose: 30–50 international units Factor IX/kg q 12 hr. Following this period, FIX levels should be maintained at 20% (20 international units Factor IX/kg q 12 hr) until healing has been achieved. May require up to 10 days of treatment.⁽²⁾

BeneFIX: Raise Factor IX level to 50% to 100% of normal. Dose q 12–24 hr for 7–10 days or until adequate wound healing occurs.⁽³⁾

Mononine: Raise Factor IX level to 25% to 50% of normal. Initial loading dose up to 75 international units/kg administered q 18–30 hr, depending on half-life and measured Factor IX levels. Continue treatment up to 10 days, depending on nature of insult.⁽⁴⁾

Surgical procedures

AlphaNine SD: Raise Factor IX level to 50% to 100% of normal preoperatively. Typical dose: 50–100 international units Factor IX/kg q 12 hr. Postoperatively, maintain levels at 50% to 100% of normal for 7–10 days, or until healing has been achieved.⁽²⁾

BeneFIX: Raise Factor IX level to 50% to 100% of normal preoperatively. Dose q 12–24 hr for 7–10 days or until healing has been achieved.⁽³⁾

Mononine: Raise Factor IX level to 50% to 100% of normal immediately prior to the procedure. Repeat dose q 18–30 hr depending on half-life and measured Factor IX levels for up to 10 days.⁽⁴⁾

Prophylaxis, primary: 25–40 international units/kg twice weekly or 15–30 international units/kg 2–3 times weekly.^(7,8) Individualize regimen based on age, venous access, and activity.

Dosage adjustment in organ dysfunction

No dosage adjustment is required.⁽²⁻⁴⁾

Maximum dosage

Mononine: 75 international units/kg⁽⁴⁾

Additives

AlphaNine SD contains ≤0.04 international units heparin, 0.2 mg dextrose, and ≤1 mcg polysorbate 80. Also contains trace amounts of Factors II, VII, and X.⁽²⁾

BeneFIX contains histidine (8 mM), 0.234% NaCl, 0.8% sucrose, glycine (208 mM), and polysorbate 80.⁽³⁾

Mononine contains histidine (10 mM), NaCl, mannitol (3%), and polysorbate 80 (0.0075%). Also contains trace amounts of Factors II, VII, and X.⁽⁴⁾

