Antihemophilic Factor (Human) (Factor VIII)

Brand names	Hemophil M, Koate-DVI, Monoclate-P
Medication error potential	Factor VIII may be confused with Factor XIII[1]
Contraindications and warnings	**Contraindications:** Hypersensitivity or intolerance to any component in the product.[1-4] Product-specific contraindications: Hemofil M, Monoclate P, hypersensitivity to mouse protein.[2,4] **Other warnings:** Hemofil M contains latex in product packaging. Avoid use in patients with latex allergy.[2] Koate-DVI contains polysorbate 80, which may cause allergic reactions in susceptible individuals, especially neonates.[3] Human antihemophilic factor (AHF) products are prepared from human pooled plasma and may carry a risk for transmission of infectious agents, despite viral attenuation processes.[2-6] Hepatitis A and B vaccination are recommended in all hemophilia patients.[5] Progressive anemia and hemolysis may occur when large or frequent doses of human AHF are administered to patients with blood groups A, B, and AB, due to trace amounts of blood group A and B isohemagglutinins.[1,4] Patients treated with AHF products should be carefully monitored for the development of Factor VIII inhibitors by appropriate clinical observations and laboratory tests. Inhibitors have been reported following administration of these products, predominantly children <5 years of age. If expected plasma Factor VIII activity levels are not attained, or if bleeding is not controlled with an expected dose, an assay that measures Factor VIII inhibitor concentration should be performed.[1-5]
Infusion-related cautions	All products have been associated with anaphylaxis-type reactions. Reduce infusion rate or temporarily discontinue if patient experiences tachycardia or allergic-type reaction.[1-4][4]
Dosage	**Individualize dosage based on coagulation studies performed prior to treatment and at regular intervals during treatment:** For every 1 international unit/kg body weight of product administered, Factor VIII level should increase by 2%; calculated dose should be adjusted to the actual vial size.[1-4] Formula[3] to calculate dosage required, based on desired increase in Factor VIII (% of normal). **Note:** This formula assumes that the patient's baseline AHF level is <1%): international units required = body weight (kg) × 0.5 × desired increase in Factor VIII (international units/dL or % of normal).[1-4] Consult individual product labeling for specific dosing recommendations.[2-4] **Minor hemorrhage (required peak postinfusion AHF level, 20% to 40%):** 10–20 international units/kg; repeat q 12–24 hr for 1–3 days until bleeding is resolved or healing is achieved. Mild superficial or early hemorrhage may respond to a single dose.[2-4] **Moderate hemorrhage (required peak postinfusion AHF level, 30% to 60%):** 15–30 international units/kg; repeat q 12–24 hr for 3–4 days until pain and disability are resolved.[2-4] **Severe/life-threatening hemorrhage** **Hemofil M (required peak postinfusion AHF level, 60% to 100%):** 30–50 international units/kg; repeat q 8–24 hr until threat is resolved.[1,2] **Koate-DVI, Monoclate P (required peak postinfusion AHF level, 80% to 100%)** **Initial:** 40–50 international units/kg **Maintenance:** 20–25 international units/kg q 8–12 hr until bleeding is resolved[3,4]

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Dosage *(cont.)*	**Minor surgery (required peak postinfusion AHF level, 30% to 80%):** 15–40 international units/kg; dose depends on procedure and specific product recommendations. For some procedures, a single dose plus oral antifibrinolytic therapy within 1 hour is sufficient; other procedures may require repeated doses q 12–24 hr until bleeding is resolved.[1-3] **Monoclate P (required peak postinfusion AHF level, 30% to 50%)** **Initial dose:** 15–25 international units/kg **Maintenance dose:** 10–15 international units/kg q 8–12 hr[4] **Major surgery (required peak pre- and postoperative AHF level, 80% to 100%):** 40–50 international units/kg 1 hour prior to surgery; repeat 18–24 hr depending on healing.[1] **Hemofil M (required peak pre- and postsurgery AHF level, 80% to 100%):** Give sufficient dose 1 hour prior to surgery; repeat q 8–24 hr depending on state of healing.[2] **Koate-DVI (required peak pre- and postsurgery AHF level, 100%):** 50 international units/kg; repeat q 6–12 hr initially and until healing complete (10–14 days).[3] **Monoclate P (required peak pre- and postsurgery AHF level, 80% to 100%):** Give sufficient dose 1 hour prior to surgery. Second dose, 50% of first priming dose should be administered 5 hours after first dose. Factor levels should be maintained to minimum of at least 30% for 10–14 days postoperatively to maintain hemostasis.[4] **Prophylaxis:** May be given on a regular schedule to prevent bleeding, usually administered 3 times a week. Dose should be individualized based on age, venous access, activity, and availability of clotting factor concentrates. Prophylactic therapy is reserved for patients with severe hemophilia. Goal is to maintain Factor VIII levels >1 international unit/dL.[5,7,8]
Dosage adjustment in organ dysfunction	No dosage adjustment required[2-4]
Maximum dosage	None reported
Additives	**Hemofil M:** Albumin, polyethylene glycol, histidine, glycine, mouse protein, tri-n-butyl phosphate, octoxynol 9[2] **Koate-DVI:** Albumin, polyethylene glycol, glycine, polysorbate 80, tri-n-butyl phosphate, calcium, aluminum, histidine[3] **Monoclate-P:** Albumin, sodium (300–450 mM/L), calcium chloride, mannitol, histidine, mouse protein[4]
Suitable diluents	**Reconstitution:** SW[2-4]
Maximum concentration	None
Preparation and delivery	Allow product to come to room temperature before reconstitution. Use transfer needle provided or syringe and needle to transfer diluent into vial of drug. Gently agitate or rotate vial after addition of diluent. Do not vigorously shake vial. Do not refrigerate after reconstitution, administer within 3 hours after reconstitution.[1-4] Use plastic syringes; proteins may adhere more to glass syringes.[1-4] Hemofil M and Monoclate P have been demonstrated to be stable at room temperature and retain activity above 80% for at least 24 hours after reconstitution.[9]