Hemophilia and Thrombosis Center
UNIVERSITY OF COLORADO
ANSCHUTZ MEDICAL CAMPUS

University of Colorado Hemophilia & Thrombosis Center Pharmacy: RECOMBINANT FACTOR VIII PRODUCTS DOSING RECOMMENDATIONS

FULL STANDARD DOSING RECOMMENDATIONS

Dosage and frequency of treatment is dependent on the level of factor VIII deficiency, the location and severity of the bleed, and the patient's individual clinical response. Patients may vary in their pharmacokinetic response (e.g., half-life, in vivo recovery) and clinical response to factor products.

One unit per kilogram body weight will raise the Factor VIII level by 2% international units per deciliter [IU/dL].

Dosage can be estimated using these standard equations:

Desired Increment in Factor VIII concentration (IU/dL or % of normal) = [Total Dose (IU) / body weight (kg)] x 2 (IU/dL per IU/kg)

OR

Required Dose (IU) = body weight (kg) x desired factor VIII Rise (IU/dL or % of normal) x 0.5 (IU/kg per IU/dL)

Dosing examples for standard recombinant Factor VIII products:

Adult Prophylaxis: 20-40 units/kg every other day or three times per week
Children <12 yo Prophylaxis: 25-50 units/kg every other day or three times per week
Minor muscle or oral bleed: 10-30 units/kg every 12-24 hours until bleeding resolution is achieved
Major muscle or joint bleed: 30-50 units/kg every 8-24 hours until bleeding resolution is achieved

University of Colorado Hemophilia & Thrombosis Center Pharmacy: RECOMBINANT FACTOR VIII PRODUCTS CHART 1 of 2

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	RECOMBINATE™	KOGENATE®FS	ADVATE™	XYNTHA®
MANUFACTURER	SHIRE (formerly BAXALTA)	BAYER	SHIRE (formerly BAXALTA)	PFIZER
US LICENSURE DATE	1992	1993	2003	2008
GENERATION OF PRODUCT (see definition below)	First Generation[1]	Second Generation[2]	Third Generation[3]	Third Generation[3] (B-Domain deleted)
CELL LINE FORMULATION, SOURCE MATERIAL	Chinese Hamster Ovary (CHO) cell line	Baby hamster kidney (BHK) cell line	Chinese Hamster Ovary (CHO) cell line	Chinese Hamster Ovary (CHO) cell line
PROTEIN PURIFICATION METHOD	-Monoclonal antibody immunoaffinity chromatography	-Ion exchange chromatography -Monoclonal antibody immunoaffinity chromatography	-Monoclonal antibody immunoaffinity chromatography	-Affinity chromatography using patented synthetic peptide affinity ligand
VIRAL INACTIVATION METHOD	Micro-Filtration; Ion exchange chromatography as shown in model virus studies	Solvent/Detergent	Solvent/Detergent	Solvent/Detergent; virus retaining nanofiltration
ALBUMIN USED IN MANUFACTURING PROCESS	Yes (Human)	Yes (Human)	No	No
STABILIZING AGENTS	Albumin	Sucrose	Trehalose, Mannitol	Sucrose
INACTIVE INGREDIENTS	Albumin (human), Ca, PEG 3350, NaCl, histidine, Polysorbate-80	Sucrose, glycine, histidine, sodium, calcium, chloride, polysorbate- 80, imidazole, tri-n-butyl phosphate, copper	Mannitol, trehalose, sodium chloride, histidine, tris, calcium chloride, polysorbate-80 and/or glutathione	NaCl, Sucrose, histidine, CaCl, polysorbate-80
SPECIFIC ACTIVITY (amount of clotting activity per weight of substance)	4,000-8,000 IU/mg of protein	~4,000 IU/mg of protein	4,000-10,000 IU/mg of protein	5,500-9,000 IU/mg of protein
MEAN HALF LIFE	14.6 ± 4.9 hrs	**Pediatric:**(4.4-18.10 yo): 10.7 hrs (mean range 7.8-15.3 hrs) **Adult (>18 yo):** 14.07 ± 2.62 hrs	**Pediatric:**1-24 mo: 8.7 ± 1.4 hrs 2-5 yo: 9.5 ± 1.8 hrs 5-12 yo: 11.2 ± 3.5 hrs 12-16 yo**:** 12.0 ± 2.9 hrs **Adult(>16 yo):** 12.0 ± 4.2 hrs	**Pediatric:**(3.7-5.8 yo): 8.3 ±2.7 hrs (14-15 yo): 6.9 ± 2.4 hrs **Adult (12-60 yo)**: 11.2 ± 6.2 hrs

1. First generation: human or animal albumin used as both nutrients in cell culture and as stabilizer in final product
2. Second generation: human albumin used as nutrient in cell culture, but not as stabilizer in final product
3. Third generation: no human or animal albumin used either as nutrient in cell culture or as stabilizer in final product

NOTE: Recombinant technology may be the ONLY product of choice for patients of the Jehovah's Witnesses faith.

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University of Colorado Hemophilia & Thrombosis Center Pharmacy: RECOMBINANT FACTOR VIII PRODUCTS CHART 1 of 2

	RECOMBINATE™	KOGENATE®FS	ADVATE™	XYNTHA®
BOX CONTENTS	Diluent: 5 mL (all sizes) Sterile water, Baxject™ II Needleless Transfer Device	Diluent: Sterile water 2.5 mL (250, 500, 1000), 5 mL (2000, 3000) vial adapter with 15 micrometer filter, infusion set	Diluent: 2 mL (250, 500, 1000, 1500), 5 mL (2000, 3000, 4000) Sterile water, Baxject™ III Needleless Transfer Device 2mL kits also contain microbore butterfly	Diluent: 4 mL sodium chloride prefilled syringe with plunger rod, vial adapter, 23G infusion set, alcohol pads, bandage, gauze SOLOFUSE: Prefilled dual-chamber syringe with lyophilized Xyntha® powder in one chamber and sodium chloride in other chamber, 23G infusion set, alcohol pads, bandage, gauze
ASSAYS AVAILABLE	250 IU, 500 IU, 1000 IU, 1500 IU, 2000 IU	250 IU,500 IU,1000 IU, 2000 IU, 3000 IU	250 IU, 500 IU,1000 IU,1500 IU, 2000 IU, 3000 IU, 4000 IU	250 IU, 500 IU, 1000 IU, 2000 IU, 3000 IU (Solofuse only)
INFUSION RATE	Infuse at a rate of ≤5 mL/minute (maximum: 5 mL/minute) Infuse within 3 hours of reconstitution.	Infuse over 1 to 15 minutes (based on patient tolerability) Infuse within 3 hours of reconstitution.	Infuse over ≤5 minutes (maximum: 10 mL/minute) Infuse within 3 hours of reconstitution.	Infuse over several minutes; adjust based on patient comfort. Do not admix or administer in same tubing as other medications. Infuse within 3 hours of reconstitution.
STORAGE REQUIREMENTS	☑Room temperature <86°F until expiration date. ☑Do not freeze. ☑ Keep the vial in the original carton and protect from light.	☑Refrigerate (36°F to 46°F) to expiration date. ☑ Room temp < 77 °F for up to 12 months. ☑Do not freeze. ☑Once product is stored at room temperature product it should not be returned to refrigerator. ☑ Keep the vial in the original carton and protect from light.	☑Refrigerate (36°F to 46°F) to expiration date. ☑Room temp < 86 °F for up to 6 months. ☑Do not freeze. ☑Once product is stored at room temperature it should not be returned to refrigerator. ☑ Keep the vial in the original carton and protect from light.	☑Refrigerate (36°F to 46°F) to expiration date. ☑Room temp < 77 °F for up to 3 months. ☑ Do not freeze. ☑Once product is stored at room temperature it should not be returned to refrigerator. ☑ Keep the vial in the original carton and protect from light.
DOSING GUIDELINES	SEE BELOW	SEE BELOW	SEE BELOW	SEE BELOW
FDA APPROVED INDICATION **FOR PATIENTS WITH HEMOPHILIA A OR FACTOR VIII DEFICIENCY ONLY** **ICD-10 DIAGNOSIS CODE D66**	Prevention and control of bleeding in adults and children: ☑ episodic bleeds ☑ perioperative management **NOT INDICATED FOR VON WILLEBRAND DISEASE**	Prevention and control of bleeding in adults and children: ☑ episodic bleeds ☑ perioperative management ☑ routine prophylaxis **NOT INDICATED FOR VON WILLEBRAND DISEASE**	Prevention and control of bleeding in adults and children: ☑ episodic bleeds ☑ perioperative management ☑ routine prophylaxis **NOT INDICATED FOR VON WILLEBRAND DISEASE**	Prevention and control of bleeding in adults and children: ☑ episodic bleeds ☑ surgical prophylaxis **NOT INDICATED FOR VON WILLEBRAND DISEASE**
COMMENTS			2 mL vials should be infused with butterfly provided to prevent factor loss due to high concentration.	

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	NOVOEIGHT®	KOLVATRY®	NUWIQ®	AFSTYLA ®
MANUFACTURER	NOVO NORDISK	BAYER	OCTAPHARMA	CSL Behring
US LICENSURE DATE	2013	2016	2015	2016
GENERATION OF PRODUCT (see definition below)	Third generation[3] (B-Domain replaced with 21 amino acid linker)	Third Generation[3]	Third generation[3] (B-Domain Deleted)	Third generation[3], single-chain B-domain deleted rFVIII
CELL LINE FORMULATION, SOURCE MATERIAL	Chinese Hamster Ovary (CHO) cell line	Baby hamster kidney (BHK) cell line	Human Embryonic Kidney (HEK) cell line	Chinese Hamster Ovary (CHO)
PROTEIN PURIFICATION METHOD	-Ion exchange chromatography antibody - Immunoaffinity chromatography	-Chromatography -Filtration	Chromatography	N/A
VIRAL INACTIVATION METHOD	Solvent/Detergent; 20-nm and gel filtration	Solvent/Detergent; 20-nm nanofiltration	Solvent/Detergent 20-nm nanofiltration	Solvent/Detergent 20 nm nanofiltration
ALBUMIN USED IN MANUFACTURING PROCESS	No	No	No	No
STABILIZING AGENTS	Sucrose	Sucrose	Sucrose	Sucrose
INACTIVE INGREDIENTS	NaCl, L-histidine, sucrose, polysorbate-80, L-methionine, calcium chloride	Glycine, sucrose, sodium chloride, calcium chloride, histidine, polysorbate-80	NaCl, sucrose, L-arginine HCl, calcium chloride dihydrate, poloxamer 188, sodium citrate dihydrate	L-histidine, polysorbate-80, calcium chloride, sodium chloride, sucrose
SPECIFIC ACTIVITY (amount of clotting activity per weight of substance)	~8340 IU/mg of protein	~4000 IU/mg of protein	~8124 IU/mg of protein	8200-16000 IU/mg
MEAN HALF LIFE	**Pediatric:**0 to <6 yo: 7.7 ± 1.8 hrs 6 to <12 yo: 10.0 ± 1.7 hrs **Adult (>12 yo):** 10.8 ± 4.9 hrs	**Pediatric:** (12-17 yo): 11.7±1.11 hrs **Adult (>12yo):** 14.3 ± 3.7 hrs	**Pediatric:** 2 to 5 yo: 11.9 ± 5.4 hrs 6 to <12 yo: 13.1 ± 2.6 hrs **Adult (>12yo):** 17.1 ± 11.2 hrs	**Chromogenic Assay** **Pediatric (0-6 yo):** 10.4 hrs. **(6-12 yo):** 10.2 hrs. **Adolescents (12-18 yo**): 14.3 hrs. **Adults (>18 yo):** 14.2 hrs.
BOX CONTENTS	Diluent: 4ml sodium chloride prefilled syringe, vial adapter w/25 micrometer filter	Diluent: Sterile water prefilled syringe: 2.5 mL (250, 500, 1000), 5 mL (2000, 3000, vial adapter with 15 micrometer filter, infusion set	Diluent: 2.5ml (all sizes) Sterile water for Injection prefilled syringe, vial adapter, butterfly needle and two alcohol swabs.	Diluent: Sterile water for Injections 2.5 mL (250, 500, 1000), 5ml (1500, 2000, 2500, 3000), Mix2Vial filter transfer set, alcohol swab

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University of Colorado Hemophilia & Thrombosis Center Pharmacy:
RECOMBINANT FACTOR VIII PRODUCTS CHART 2 of 2

	NOVOEIGHT®	**KOLVATRY®**	**NUWIQ®**	**AFSTYLA ®**
ASSAYS AVAILABLE	250 IU, 500 IU, 1000 IU, 1500 IU, 2000 IU, 3000 IU	250 IU, 500 IU, 1000 IU, 2000 IU,3000 IU	250 IU, 500 IU, 1000 IU, 2000 IU	250 IU, 500 IU, 1000 IU, 1500 IU, 2000 IU, 2500 IU, 3000 IU
INFUSION RATE	Infuse over 2 to 5 minutes Infuse within 4 hours of reconstitution.	Infuse over 1 to 15 minutes (based on patient tolerability) Infuse within 3 hours of reconstitution.	Infuse at maximum rate of 4ml per minute, adjust based on patient comfort. Infuse within 3 hours of reconstitution.	Infuse at maximum rate of 10 mL per minute (determined by patient comfort level) Infuse within 4 hours of reconstitution.
STORAGE REQUIREMENTS	☑Refrigerate (36°F to 46°F) to expiration date. ☑ Room temp < 86 °F for up to 12 months. ☑Do not freeze. ☑Once product is stored at room temperature it should not be returned to refrigerator. ☑ Keep the vial in the original carton and protect from light.	☑Refrigerate (36°F to 46°F) to expiration date. ☑ Room temperature <77°F for up to 3 months. ☑Do not freeze. ☑Once product is stored at room temperature it should not be returned to refrigerator. ☑ Keep the vial in the original carton and protect from light.	☑Refrigerate (36°F to 46°F) to expiration date. ☑ Room temperature <77°F for up to 3 months. ☑ Do not freeze. ☑ Once product is stored at room temperature it should not be returned to refrigerator. ☑ Keep the vial in the original carton and protect from light.	☑Refrigerate (36°F to 46°F) to expiration date. ☑ Room temp < 77 °F for up to 3 months. ☑ Do not freeze. ☑ Once product is stored at room temperature product it should not be returned to refrigerator. ☑ Keep the vial in the original carton and protect from light.
DOSING GUIDELINES	**Children ≤ 12 yo:** 25-60 IU/kg 3 times weekly or 25-50 IU/kg every other day **Adults ≥ 12 yo**: 25-50 IU/kg three times a week or 20-40 IU/kg every other day	**Children ≤ 12 yo:** 25-50 IU/kg 2 times, per week, 3 times per week or every other day **Adults/adolescents:** 20-40 IU/kg 2 or 3 times per week	Prophylaxis: **Children 2-11yo**: 30-50 IU/kg every other day **Adolescents 12-17 yo:** 30-40 IU/kg every other day	**Children<12 yo prophylaxis:** 30-50 IU/kg/dose 2 to 3 times per week. More frequent or higher doses may be required in this age group. **Adults and adolescents prophylaxis:** 20-50 IU/kg/dose 2 to 3 times per week.
FDA APPROVED INDICATION **FOR PATIENTS WITH HEMOPHILIA A OR FACTOR VIII DEFICIENCY ONLY ICD-10 DIAGNOSIS CODE D66**	Prevention and control of bleeding in adults and children: ☑ episodic bleeds ☑ perioperative management ☑ routine prophylaxis **NOT INDICATED FOR VON WILLEBRAND DISEASE**	Prevention and control of bleeding in adults and children: ☑ episodic bleeds ☑ perioperative management ☑ routine prophylaxis **NOT INDICATED FOR VON WILLEBRAND DISEASE**	Prevention and control of bleeding in adults and children: ☑ episodic bleeds ☑ perioperative management ☑ routine prophylaxis **NOT INDICATED FOR VON WILLEBRAND DISEASE**	Prevention and control of bleeding in adults and children: ☑ episodic bleeds ☑ perioperative management ☑ routine prophylaxis **NOT INDICATED FOR VON WILLEBRAND DISEASE**
COMMENTS		Due to narrow internal tip diameter of glass syringe, IV systems and port adaptors containing an internal spike are known to have incompatibility issues. Attach an appropriately sized plastic syringe that is compatible with port adaptor or other connector to administer.		If the one-stage clotting assay is used, multiply the result by a conversion factor of 2 to determine the patient's FVIII activity level.

1. First generation: human or animal albumin used as both nutrients in cell culture and as stabilizer in final product
2. Second generation: human albumin used as nutrient in cell culture, but not as stabilizer in final product
3. Third generation: no human or animal albumin used either as nutrient in cell culture or as stabilizer in final product

NOTE: Recombinant technology may be the ONLY product of choice for patients of the Jehovah's Witnesses faith.

University of Colorado Hemophilia & Thrombosis Center Pharmacy: RECOMBINANT FACTOR VIII CONCENTRATES EXTENDED HALF-LIFE

Hemophilia and Thrombosis Center
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	ELOCTATE®	ADYNOVATE™	JIVI®
MANUFACTURER	BIOVERATIV (FORMERLY BIOGEN IDEC)	SHIRE (FORMERLY BAXTER)	BAYER
US LICENSURE DATE	2014	2015	2018
GENERATION OF PRODUCT (see definition below)	Third generation[1] (Fc Fusion Protein (B-Domain deleted)	Third generation (Pegylated)	Third generation B-Domain deleted (Peglated)
CELL LINE FORMULATION, SOURCE MATERIAL	Human embryonic kidney (HEK) cell line	Chinese Hamster Ovary (CHO) cell line	Baby Hamster Kidney (BHK) cell line
PROTEIN PURIFICATION METHOD	Affinity chromatography	Monoclonal antibody immunoaffinity chromatography	Chromatography and ultrafiltration
VIRAL INACTIVATION METHOD	Detergent and filtration	Solvent/Detergent	Detergent and filtration
ALBUMIN USED IN MANUFACTURING PROCESS	No	No	No
STABILIZING AGENTS	Sucrose	Mannitol	Sucrose
INACTIVE INGREDIENTS	Sucrose, NaCl, L-histidine, calcium chloride, polysorbate-20	Tris (hydroxymethyl) aminomethane, calcium chloride, mannitol, sodium chloride, trehalose dihydrate, glutathione, histidine, polysorbate -80	Glycine, sucrose, histidine, sodium chloride, calcium chloride, polysorbate-80
SPECIFIC ACTIVITY (amount of clotting activity per weight of substance)	4,000-10,000 IU/mg of protein	2700-8000 IU/mg protein	10,000 IU/mg of protein
MEAN HALF LIFE	**Pediatrics:** 1-5 yo: 12.7 hours 6-11 yo: 14.9 hours 12-17 yo: 16.4 hours **Adults (>18 yo):** 19.7 hours	**Pediatric:** <6 yo: 11.8 ± 2.43 hours 6-<12 yo: 12.4 ± 1.67 hours 12-18 yo: 13.43 ± 4.05 hours **Adults (>18yo)** : 14.69 ± 3.79 hours	**Adults (>12 yo):** 17.9 ± 4.0 hours (chromogenic) 17.4 ± 3.8 hours (one-stage assay)
Ratio of the mean half-life of long-acting factor/rFVIII	1.5	1.4	1.4
BOX CONTENTS	Diluent: 3 mL Sterile Water for Injection prefilled syringe, vial adapter	Diluent: 2 mL (250, 500, 1000 IU), 5mL (2000 IU) Sterile Water for injection , BAXJECT III Hi-flow transfer device	Diluent: 2.5 mL Sterile Water for Injection prefilled syringe, vial adapter w/filter, 25G butterfly needle
ASSAYS AVAILABLE	250 IU, 500 IU, 750 IU, 1000 IU, 1500 IU, 2000 IU, 3000 IU, 4000 IU, 5000 IU, 6000 IU	250 IU, 500IU, 1000 IU, 2000 IU	500 IU, 1000 IU, 2000 IU, 3000 IU
INFUSION RATE	Infuse at a rate of ≤10 mL/minute (maximum: 10 mL/minute) Infuse within 3 hours of reconstitution.	Infuse at a rate of ≤ 5 minutes (maximum: 10 mL/minute) Infuse within 3 hours of reconstitution.	Infuse at a rate of 1-15 minutes (maximum: 2.5 mL/minute) Infuse within 3 hours of reconstitution.

University of Colorado Hemophilia & Thrombosis Center Pharmacy: RECOMBINANT FACTOR VIII CONCENTRATES EXTENDED HALF-LIFE

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	ELOCTATE®	ADYNOVATE™	JIVI®
STORAGE REQUIREMENTS	▫Refrigerate (36°F to 46°F) to expiration date or store at room temp < 86 °F for up to 6 months ▫Do not freeze ▫ Once stored at room temperature, do not return the product to the refrigerator ▫Store vial in original box and protect from light	▫Refrigerate (36°F to 46°F) to expiration date or store at room temp < 86 °F for up to 3 months ▫Do not freeze ▫ Once stored at room temperature, do not return the product to the refrigerator ▫ Store vial in original box and protect from light	▫Refrigerate (36°F to 46°F) to expiration date or store at room temp < 77 °F for up to 6 months ▫Do not freeze ▫ Once stored at room temperature, do not return the product to the refrigerator ▫ Store vial in original box and protect from light
DOSING GUIDELINES	Prophylaxis: **Children < 6yo**: Starting regimen 50 IU/kg twice a weekly. Adjust dose based on patient response with dosing range of 25-65 IU/kg every 3-5 days. More frequent or higher doses of up to 80 IU/kg may be required. **Adults/children > 6yo:** 50 units/kg every 4 days or 25-65 units/kg every 3-5 days. SEE PRESCRIBING INFORMATION FOR OTHER REGIMENS	Prophylaxis: **Children < 12 yo**: 55 units/kg twice a week (with max dose of 70 units/kg). Adjust dose based on the patient's clinical response. **Adults/children >12 yo:** 40-50 units/kg twice a week. Adjust dose based on the patient's clinical response. SEE PRESCRIBIING INFORMATION FOR OTHER REGIMENS.	Prophylaxis: **Adults/children >12 yo:** 30-40 units/kg twice weekly Based on the bleeding episodes the regime may be adjusted to 45-60 units/kg every 5 days. A regime may be individually adjusted to less or more frequent dosing. The total recommended max dose per infusion is approximately 6000 IU. SEE PRESCRIBIING INFORMATION FOR OTHER REGIMENS.
FDA APPROVED INDICATION FOR PATIENTS WITH HEMOPHILIA A OR FACTOR VIII DEFICIENCY ONLY **ICD-10 DIAGNOSIS CODE D66** **NOT INDICATED FOR VON WILLEBRAND DISEASE**	Prevention and control of bleeding in adults and children: ☑ On-demand treatment ☑ Routine prophylaxis ☑ Perioperative management	Prevention and control of bleeding in adults and children: ☑ On-demand treatment ☑ Routine prophylaxis ☑ Perioperative management	Prevention and control of bleeding in adults: ☑ On-demand treatment ☑ Routine prophylaxis ☑ Perioperative management Not indicated for use in children <12 years old

1. Third generation rFVIII: : No human or animal albumin used either as nutrient in cell culture or as stabilizer in final product

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University of Colorado Hemophilia & Thrombosis Center Pharmacy:
PLASMA DERIVED FACTOR VIII CONCENTRATES

Hemophilia and Thrombosis Center
UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS

	ALPHANATE-SD®	KOATE-DVI®	MONOCLATE-P®	HEMOFIL-M™
MANUFACTURER	GRIFOLS	GRIFOLS FOR KEDRION	CSL BEHRING	SHIRE (formerly Baxalta)
US LISCENSURE DATE	1997 Hemophilia A; 2007 VWD	1986 Hemophilia A; 1999 VWD	1990	1988
PROTEIN PURIFICATION METHOD	-Cryoprecipitation -PEG precipitation -Affinity chromatography -Salt/glycine precipitation	-Fractionation -Gel Chromatography	-Monoclonal antibody immuneoaffinity chromatography	-Monoclonal antibody immunoaffinity chromatography -Ion exchange chromatography
VIRAL INACTIVATION METHOD	-Solvent/ Detergent -Dry Heat Cycle	-Solvent /Detergent -Dry Heat Cycle	-Pasteurization	-Nanofiltration -Solvent/Detergent
INACTIVE INGREDIENTS	Albumin (Human), arginine, histidine	PEG, glycine, polysorbate-80, tri-n-butyl phosphate, calcium, aluminum, histidine, Albumin	Calcium chloride, albumin, mannitol, histidine, pH is adjusted with hydrochloric acid and/or sodium hydroxide.	Albumin, PEG 3350, histidine, glycine, mouse protein, tri-n-butyl phosphate, octoxynol-9
SPECIFIC ACTIVITY (amount of clotting activity per weight of substance)	≥5 units FVIII/mg of protein, final product	9-22 units FVIII/mg of protein, final product	4-10 units FVIII/mg of protein, final product	2-22 units FVIII/mg protein, final product
MEAN HALF LIFE	17.9 ± 9.6 hours	~16.12 hours	~17.5 hours	14.8 ±3.0 hours
BOX CONTENTS	Diluent: 5 mL (250, 500), 10 mL (1000, 1500, 2000) Sterile Water for Injection, Mix2Vial filter transfer set	Diluent: 5 mL (250, 500), 10 mL (1000) Sterile Water for Injection; transfer needle, filter needle, winged infusion set	Diluent: 2.5 mL (250), 5 mL (500), 10 mL (1000, 2000) Sterile Water for Injection, transfer needle, vented filter spike, filter needle, winged infusion set, alcohol swabs	Diluent: 10 mL (all sizes) Sterile Water for Injection, transfer needle, filter needle
ASSAYS AVAILABLE	250 IU, 500 IU, 1000 IU, 1500 IU, 2000 IU	250 IU, 500 IU, 1000 IU	250 IU, 500 IU, 1000 IU, 1500 IU	250 IU, 500 IU, 1000 IU, 1700 IU
INFUSION RATE	≤10 mL/minute Use within 3 hours of reconstitution.	Full dose in 5-10 minutes Use within 3 hours of reconstitution.	At a comfortable rate (2mL/minute) Use within 3 hours of reconstitution.	Up to 10 mL/minute Use within 3 hours of reconstitution.

University of Colorado Hemophilia & Thrombosis Center Pharmacy: PLASMA DERIVED FACTOR VIII CONCENTRATES

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	ALPHANATE-SD®	KOATE-DVI®	MONOCLATE-P®	HEMOFIL-M™
STORAGE REQUIREMENTS	▫Refrigerate or store at room temperature 25°C (≤ 77°F) up to expiration date. ▫Do not freeze.	▫Refrigerate 2°C to 8°C (36°F to 46°F) to expiration date ▫Store at room temp 25°C (< 77 °F)for up to 6 months. ▫Do not freeze.	▫Refrigerate 2°C to 8°C (36°F to 46°F) to expiration date. ▫Store at room temp 25°C (< 77 °F) for up to 6 months. ▫Do not freeze.	▫Refrigerate or at room temperature 30°C (≤86°F) until expiration date. ▫Do not freeze.
FDA APPROVED INDICATION **FOR PATIENTS WITH HEMOPHILIA A OR FACTOR VIII DEFICIENCY** **ICD-10 DIAGNOSIS CODE** **D66** **VON WILLEBRAND DISEASE** **ICD-10 DIAGNOSIS CODE** **D68**	Prevention and control of bleeding in Hemophilia A adults: Episodic bleeds Perioperative management Von Willebrands Disease in adults and children: ☑ Perioperative management in patients in whom DDAVP is either ineffective or contraindicated.	Prevention and control of bleeding in Hemophilia A adults: Episodic bleeds Perioperative management	Prevention and control of bleeding in Hemophilia A adults: Episodic bleeds Perioperative management	Prevention and control of bleeding in Hemophilia A adults: Episodic bleeds
DOSING GUIDELINES	SEE BELOW	SEE BELOW	SEE BELOW	SEE BELOW
COMMENTS	**NOT INDICATED FOR PATIENTS WITH SEVERE VON WILLEBRAND DISEASE TYPE III**	Koate-DVI contains naturally occurring VWF; **NOT INDICATED FOR THE TREATMENT OF VON WILLEBRAND DISEASE**	Contains reduced amounts of VWF:Ag Currently only available in 1000 IU & 1500 IU assay size; **NOT INDICATED FOR THE TREATMENT OF VON WILLEBRAND DISEASE**	

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University of Colorado Hemophilia & Thrombosis Center Pharmacy
MEDICATION CHART DISCLAIMER

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Disclaimer: Information regarding factor products has been derived from the manufacturer FDA-approved Prescribing Information sheets and other sources and compiled by the staff at the Hemophilia & Thrombosis Center Pharmacy at the University of Colorado. Although every effort is made to assure accuracy, the information was not reviewed by the manufacturer of any particular drug. Information has been provided only as an easily accessible reference of basic information. This information is provided as is without any guarantees or warranty. Dosing information is not intended to replace a physician's judgment on the appropriate dosing regimen for each individual patient.