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REFERENCE CATALOG

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ADVATE

Product Name	ADVATE
Manufacturer	Shire
Manufacturer Contact Number	(800) 828-2088
Product Descriptor	Antihemophilic Factor (Recombinant)
Indications	For use in children and adults with hemophilia A for: • Control and prevention of bleeding episodes • Perioperative management • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes Not indicated for the treatment of von Willebrand disease.
Nominal Dosage Strengths[1]	250 IU, 500 IU, 1000 IU, 1500 IU, 2000 IU, 3000 IU, 4000 IU[2]
Contraindications	Life-threatening hypersensitivity reactions, including anaphylaxis, to mouse or hamster protein or other product constituents (mannitol, trehalose, sodium chloride, histidine, Tris, calcium chloride, polysorbate 80 and/or glutathione).
Viral Removal/ Inactivation	Solvent/detergent treatment
Serum Half-Life (Mean)[3]	12.03 ± 4.15 hours
Stabilizers/Excipients	Mannitol, trehalose, sodium chloride, histidine, Tris, calcium chloride, polysorbate 80, glutathione
Rate of Administration[4]	Inject intravenously over a period of ≤ 5 minutes (maximum rate 10 mL/minute)
Other Administration Considerations[4]	Inspect for particulate matter and discoloration prior to administration. Administer at room temperature not more than 3 hours after reconstitution.
Diluent Volume	2 mL (250 through 1500 IU dosages) or 5 mL (2000 through 4000 IU dosages)
Other Package Contents	SWFI diluent (2 mL or 5 mL) and Baxject II Needleless Transfer Device; one Terumo Microbore Infusion set (2 mL only)
Storage[4]	Refrigerate at 2°C to 8°C (36°F to 46°F) in powder form. May be stored at room temperature up to 30°C (86°F) for up to 6 months, not to exceed the expiration date. Do not use beyond the expiration date printed on the vial or 6 months past the date noted on the product carton that was removed from refrigeration, whichever is earlier. After storage at room temperature, the product must not be returned to the refrigerator. Do not freeze.

Helixate® FS

Product Name	Helixate® FS
Manufacturer	CSL Behring
Manufacturer Contact Number	(800) 504-5434
Product Descriptor	Antihemophilic Factor (Recombinant), Formulated with Sucrose
Indications	• Control and prevention of bleeding episodes in adults and children (0-16 years) with hemophilia A. • Surgical prophylaxis in adults and children with hemophilia A. • Routine prophylaxis to reduce the frequency of bleeding episodes and the risk of joint damage in children with hemophilia A with no pre-existing joint damage. Not indicated for the treatment of von Willebrand disease.
Nominal Dosage Strengths[1]	250 IU, 500 IU, 1000 IU, 2000 IU, 3000 IU
Contraindications	Patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including mouse or hamster proteins.
Viral Removal/Inactivation	Solvent/detergent treatment
Serum Half-Life (Mean)[3]	13.74 ± 1.82 hours initially 14.60 ± 4.38 hours at week 24
Stabilizers/Excipients	Sucrose, glycine, histidine
Rate of Administration[4]	Administer over 1 to 15 minutes; rate should be adapted to the response of each individual patient.
Other Administration Considerations[4]	Inspect for particulate matter and discoloration prior to administration. The reconstituted product must be administered within 3 hours after reconstitution.
Diluent Volume	250 IU/500 IU/1000 IU = 2.5 mL; 2000 IU/3000 IU = 5 mL
Other Package Contents	SWFI diluent and Mix2Vial® filter transfer set
Storage[4]	Store under refrigeration at 2°C to 8°C (36°F to 46°F) for up to 30 months from the date of manufacture. Within this period, product may be stored for a period up to 12 months, up to 25°C (77°F), such as in home treatment situations. Once stored at room temperature, the product must not be returned to the refrigerator. Do not freeze. Protect from extreme exposure to light and store the lyophilized powder in the carton prior to use.

Kogenate® FS

Product Name	Kogenate® FS
Manufacturer	Bayer
Manufacturer Contact Number	(800) 288-8374
Product Descriptor	Antihemophilic Factor (Recombinant) Formulated with Sucrose
Indications	• Control and prevention of bleeding episodes in adults and children with hemophilia A. • Perioperative management in adults and children with hemophilia A. • Routine prophylaxis to prevent or reduce the frequency of bleeding in children with hemophilia A and to reduce the risk of joint damage in children without pre-existing joint damage. • Routine prophylaxis to prevent or reduce the frequency of bleeding in adults with hemophilia A. Not indicated for the treatment of von Willebrand disease.
Nominal Dosage Strengths[1]	250 IU, 500 IU, 1000 IU, 2000 IU, 3000 IU
Contraindications	Patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including mouse or hamster proteins.
Viral Removal/ Inactivation	Solvent/detergent treatment
Serum Half-Life (Mean)[3]	13.74 ± 1.82 hours initially 14.60 ± 4.38 hours at 24 weeks
Stabilizers/Excipients	Sucrose, glycine, histidine
Rate of Administration[4]	May be administered over a period of 1 to 15 minutes. However, the rate should be adapted to the response of each individual patient.
Other Administration Considerations[4]	Inspect visually for particulate matter and discoloration. Administer within 3 hours after reconstitution.
Diluent Volume	250 IU/500 IU/1000 IU = 2.5 mL; 2000 IU/3000 IU = 5 mL
Other Package Contents	Kogenate FS is supplied in 3 configurations: • with Bio-Set® • with vial adapter • with double-ended transfer needle. For other package contents, see section 16.1 (How Supplied) in full prescribing information.
Storage[4]	Store under refrigeration at 2°C to 8°C (36°F to 46°F). Lyophilized powder may be stored at room temperature up to 25°C (77°F) for up to 12 months, such as in home treatment situations. Do not freeze. Once stored at room temperature, do not return to the refrigerator. Protect from extreme exposure to light and store the lyophilized powder in the carton prior to use.

KOVALTRY®

Product Name	KOVALTRY®
Manufacturer	Bayer
Manufacturer Contact Number	(800) 288-8374
Product Descriptor	Antihemophilic Factor (Recombinant)
Indications	In adults and children with hemophilia A: • On-demand treatment and control of bleeding episodes • Perioperative management of bleeding • Routine prophylaxis to reduce the frequency of bleeding episodes Not indicated for the treatment of von Willebrand disease.
Nominal Dosage Strengths[1]	250 IU, 500 IU, 1000 IU, 2000 IU, 3000 IU
Contraindications	Patients who have history of hypersensitivity reactions to the active substance, to any of the excipients, or to mouse or hamster protein.
Specific Viral Clearance	Detergent, nanofiltration
Serum Half-Life (Mean)[3]	14.3 ± 3.7 hours
Stabilizers/Excipients	Glycine, sucrose, sodium chloride, calcium chloride, histidine and polysorbate 80.
Rate of Administration[4]	The entire dose of Kovaltry can usually be infused within 1 to 15 minutes. Adapt the rate of administration to the response of each individual patient.
Other Administration Considerations[4]	Inspect reconstituted product for particulate matter and discoloration prior to administration. Administer as soon as possible; if not, store at room temperature for no longer than 3 hours.
Diluent Volume	250 IU/500 IU/1000 IU = 2.5 mL; 2000 IU/3000 IU = 5.0 mL
Other Package Contents	Vial adapter, 15-µm filter, prefilled diluent glass barrel syringe, administration set
Storage[4]	Store at 2°C to 8°C (36°F to 46°F) for up to 30 months from the date of manufacture. Within this period, may be stored for a single period of up to 12 months at temperatures up to 25°C (77°F). Once stored at room temperature, do not return the product to the refrigerator; shelf life expires after room temperature storage for 12 months or expiration date on the product vial, whichever is earlier. Do not freeze.

Novoeight®

Product Name	Novoeight®
Manufacturer	Novo Nordisk
Manufacturer Contact Number	(877) 668-6777
Product Descriptor	Antihemophilic Factor (Recombinant)
Indications	In adults and children with hemophilia A: • Control and prevention of bleeding • Perioperative management • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes. Not indicated for the treatment of von Willebrand disease.
Nominal Dosage Strengths[1]	250 IU, 500 IU, 1500 IU, 2000 IU, 3000 IU
Contraindications	Patients who have had life-threatening hypersensitivity reactions, including anaphylaxis, to Novoeight or its components (including traces of hamster proteins).
Viral Removal/ Inactivation	Detergent treatment, nanofiltration
Serum Half-Life (Mean)[3]	10.8 hours (clotting assay) 12.0 hours (chromogenic assay)
Stabilizers/Excipients	Sodium chloride, L-histidine, sucrose, polysorbate 80, L-methionine, calcium chloride dihydrate.
Rate of Administration[4]	Inject the reconstituted product intravenously slowly over 2 to 5 minutes.
Other Administration Considerations[4]	Inspect visually for particulate matter and discoloration. Administer within 3 hours after reconstitution.
Diluent Volume	4 mL
Other Package Contents	MixPro® pre-filled diluent syringe containing 0.9% NaCl solution, and sterile vial adapter with 25 micrometer filter, which serves as a needleless reconstitution device.
Storage[4]	Store under refrigeration at 2°C to 8°C (36°F to 46°F) for up to 30 months from the date of manufacture. Within the 30-month period, Novoeight may also be stored at room temperature not to exceed 30°C (86°F) for up to 12 months.

NUWIQ®

Product Name	NUWIQ®
Manufacturer	Octapharma USA
Manufacturer Contact Number	(888) 429-4535
Product Descriptor	Antihemophilic Factor (Recombinant)
Indications	In adults and children with hemophilia A: • On-demand treatment and control of bleeding episodes • Perioperative management of bleeding • Routine prophylaxis to reduce frequency of bleeding episodes Not indicated for the treatment of von Willebrand disease.
Nominal Dosage Strengths[1]	250 IU, 500 IU, 1000 IU, 2000 IU
Contraindications	History of life-threatening hypersensititivy reactions, including anaphylaxis, to the product or its components.
Specific Viral Clearance	Solvent/detergent treatment, nanofiltration
Serum Half-Life (Mean)[3]	17.1 hours ± 11.2 hours
Stabilizers/Excipients	Sodium chloride, sucrose, L-arginine hydrochloride, calcium chloride dihydrate, poloxamer 188, sodium citrate dihydrate
Rate of Administration[4]	Maximum infusion rate of 4 mL/minute
Other Administration Considerations[4]	Inspect reconstituted product for particulate matter and discoloration prior to administration. Do not use if particulate matter or discoloration is observed. Do not administer in the same tubing or container as other medications.
Diluent Volume	2.5 mL
Other Package Contents	SWFI, vial adapter, butterfly needle, two alcohol swabs.
Storage[4]	Store at 2°C to 8°C (36°F to 46°F) for up to 24 months. Do not freeze. May store at room temperature (up to 25°C [77°F]) for a single period not exceeding 3 months. After storage at room temperature, do not return the product to the refrigerator.

RECOMBINATE

Product Name	RECOMBINATE
Manufacturer	Shire
Manufacturer Contact Number	(800) 828-2088
Product Descriptor	Antihemophilic Factor (Recombinant)
Indications	• Prevention and control of hemorrhagic episodes in persons with hemophilia A. • Perioperative management of patients with hemophilia A. Can be of therapeutic value in patients with acquired factor VIII inhibitors not exceeding 10 Bethesda Units per mL. Not indicated for the treatment of von Willebrand disease.
Nominal Dosage Strengths[1]	220-400 IU, 401-800 IU, 801-1240 IU, 1241-1800 IU, 1801-2400 IU
Contraindications	Patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including bovine, mouse or hamster proteins.
Viral Removal/ Inactivation	None
Serum Half-Life (Mean)[3]	14.6 ± 4.9 hours
Stabilizers/Excipients	Albumin (human), calcium, polyethylene glycol, sodium, histidine, polysorbate 80
Rate of Administration[4]	Up to 5 mL/minute when supplied with 5 mL diluent or up to 10 mL/minute when supplied with 10 mL diluent
Other Administration Considerations[4]	Inspect visually for particulate matter and discoloration prior to administration. Administer the reconstituted product at room temperature. Administer not more than 3 hours after reconstitution.
Diluent Volume	5 mL
Other Package Contents	5 mL and BAXJECT II Needleless Transfer Device
Storage[4]	Refrigerate at 2°C to 8°C (36°F to 46°F) or store at room temperature, not to exceed 30°C (86°F). Avoid freezing to prevent damage to the diluent vial.

XYNTHA®

Product Name	XYNTHA®
Manufacturer	Pfizer
Manufacturer Contact Number	(800) 438-1985
Product Descriptor	Antihemophilic Factor (Recombinant)
Indications	• Control and prevention of bleeding episodes in patients with hemophilia A. • Surgical prophylaxis in patients with hemophilia A. Not indicated for the treatment of von Willebrand disease.
Nominal Dosage Strengths[1]	250 IU, 500 IU, 1000 IU, 2000 IU, 3000 IU
Contraindications	Patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including hamster proteins.
Viral Removal/Inactivation	Solvent/detergent treatment, nanofiltration
Serum Half-Life (Mean)[3]	11.2 ± 5.0 hours initially 11.8 ± 6.2 hours at month 6
Stabilization	Sucrose, polysorbate 80, L-histidine, calcium chloride
Rate of Administration[4]	Inject reconstituted product intravenously over several minutes. The rate of administration should be determined by the patient's comfort level.
Other Administration Considerations[4]	Warm powder and prefilled diluent syringe to room temperature. Inspect visually for particulate matter before administration. Should be administered within 3 hours after reconstitution.
Diluent Volume	4 mL
Other Package Contents	(1) Prefilled diluent syringe containing 4 mL 0.9% NaCl with plunger rod for assembly, infusion set, (2) alcohol swabs, (1) bandage and (1) gauze pad; or (2) Xyntha Solofuse kits[4]
Storage[4]	Refer to full prescribing information for product packaged with either prefilled diluent syringe or Xyntha Solofuse. Do not freeze to prevent damage to the prefilled diluent syringe or Xyntha Solofuse. During storage, avoid prolonged exposure to light.

ADYNOVATE

Product Name	ADYNOVATE
Manufacturer	Shire
Manufacturer Contact Number	(800) 828-2088
Product Descriptor	Antihemophilic Factor (Recombinant), PEGylated
Indications	In adolescent and adult patients (12 years and older) with hemophilia A for: • On-demand treatment and control of bleeding episodes • Routine prophylaxis to reduce the frequency of bleeding episodes. Not indicated for the treatment of von Willebrand disease.
Nominal Dosage Strengths[1]	250 IU, 500 IU, 1000 IU, 2000 IU
Contraindications	History of prior anaphylactic reaction to ADYNOVATE, the parent molecule (ADVATE), mouse or hamster protein, or excipients of ADYNOVATE.
Viral Removal/ Inactivation	Solvent/detergent treatment
Serum Half-Life (Mean)[3]	14.69 ± 3.79 hours
Stabilizers/Excipients	Tris (hydroxymethyl) aminomethane, calcium chloride, mannitol, sodium chloride, trehalose dihydrate, glutathione, histidine, polysorbate 80
Rate of Administration[4]	Maximum infusion rate of 10 mL/minute
Other Administration Considerations[4]	Inspect reconstituted solution for particulate matter and discoloration prior to administration. The solution should be clear and colorless. Do not administer if particulate matter or discoloration is observed. Administer as soon as possible, but no later than 3 hours after reconstitution.
Diluent Volume	5 mL
Other Package Contents	SWFI, BAXJECT III reconstitution system
Storage[4]	Store at 2°C to 8°C (36°F to 46°F). Do not freeze. May be stored at room temperature up to 30°C (86°F) for a period of up to 1 month. After storing at room temperature, do not return the product to the refrigerator.

AFSTYLA®

Product Name	AFSTYLA®
Manufacturer	CSL Behring
Manufacturer Contact Number	(800) 504-5434
Product Descriptor	Antihemophilic Factor (Recombinant), Single Chain
Indications	In adults and children with hemophilia A for: • On-demand treatment and control of bleeding episodes • Routine prophylaxis to reduce the frequency of bleeding episodes • Perioperative management of bleeding. Not indicated for the treatment of von Willebrand disease.
Nominal Dosage Strengths[1]	250 IU, 500 IU, 1000 IU, 2000 IU, 3000 IU
Contraindications	Do not use in patients who have had life-threatening hypersensitivity reactions, including anaphylaxis to AFSTYLA or its excipients, or hamster proteins.
Viral Removal/ Inactivation	Solvent/detergent treatment, nanofiltration
Serum Half-Life (Mean)[3]	14.2 hours
Stabilization	L-histidine, polysorbate 80, calcium chloride, sodium chloride, sucrose
Rate of Administration[4]	Do not exceed infusion rate of 10 mL per minute.
Other Administration Considerations[4]	Inspect for particulate matter prior to administration; the solution should be free from visible particles. Administer at room temperature within 4 hours after reconstitution.
Diluent Volume	250 IU/500 IU/1000 IU = 2.5 mL; 2000 IU/3000 IU = 5 mL
Other Package Contents	SWFI, Mix2Vial® filter transfer set, alcohol swab
Storage[4]	Store in powder form at 2°C to 8°C (36°F to 46°F). Do not freeze. Can be stored at room temperature, not to exceed 25°C (77°F), for a single period of up to 3 months, within the expiration date. Once stored at room temperature, do not return the product to the refrigerator. The shelf-life then expires after storage at room temperature for 3 months, or after the expiration date on the product vial, whichever is earlier.

Product Name	ELOCTATE®
Manufacturer	Biogen
Manufacturer Contact Number	(855) 693-5628
Product Descriptor	Antihemophilic Factor (Recombinant), Fc Fusion Protein
Indications	In adults and children with hemophilia A for: • Control and prevention of bleeding episodes • Perioperative management (surgical prophylaxis) • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes Not indicated for the treatment of von Willebrand disease.
Nominal Dosage Strengths[1]	250 IU, 500 IU, 750 IU, 1000 IU, 1500 IU, 2000 IU, 3000 IU
Contraindications	Patients who have had life-threatening hypersensitivity reactions to ELOCTATE, including anaphylaxis.
Viral Removal/ Inactivation	Detergent treatment, 15 nm filtration
Serum Half-Life (Mean)[3]	19.7 ± 2.3 hours
Stabilizers/Excipients	Sucrose, L-histidine, calcium chloride and polysorbate 20
Rate of Administration[4]	Should be determined by the patient's comfort level, and no faster than 10 mL per minute.
Other Administration Considerations[4]	Administer within 3 hours of reconstitution. Do not refrigerate after reconstitution. Protect from direct sunlight. Do not use if the reconstituted solution is cloudy or has particulate matter. Do not administer in the same tubing or container with other medications.
Diluent Volume	3 mL
Other Package Contents	Prefilled syringe containing 3 mL SWFI and a sterile vial adapter (reconstitution device)
Storage[4]	Store in powder form at 2°C to 8°C (36°F to 46°F). Do not freeze to prevent damage to the diluent syringe. May be stored at room temperature, not to exceed 30°C (86°F) for a single period of up to 6 months. After storage at room temperature, do not return the product to the refrigerator. Reconstituted product may be stored at room temperature, not to exceed 30°C (86°F) for up to 3 hours.

HEMOFIL M

Product Name	HEMOFIL M
Manufacturer	Shire
Manufacturer Contact Number	(800) 828-2088
Product Descriptor	Antihemophilic Factor (Human), Method M, Monoclonal Purified
Indications	Prevention and control of hemorrhagic episodes in hemophilia A. Not indicated for the treatment of von Willebrand disease.
Nominal Dosage Strengths[1]	250 IU, 500 IU, 1000 IU, 1500 IU
Contraindications	Known hypersensitivity to the active substance, to excipients, or to mouse protein.
Viral Removal/ Inactivation	Solvent/detergent treatment
Serum Half-Life (Mean)[3]	14.8 ± 3.0 hours
Stabilization	Albumin (human)
Rate of Administration[4]	Up to 10 mL/minute
Other Administration Considerations[4]	Inspect for particulate matter and discoloration prior to administration. Administer at room temperature. Administer not more than 3 hours after reconstitution.
Diluent Volume	10 mL
Other Package Contents	SWFI, a double-ended needle and a filter needle
Storage[4]	Refrigerate at 2°C to 8°C (36°F to 46°F) or at room temperature, not to exceed 30°C (86°F). Avoid freezing to prevent damage to the diluent bottle.

Koāte®-DVI

Product Name	Koāte®-DVI
Manufacturer	Kedrion Biopharma
Manufacturer Contact Number	(855) 353-7466
Product Descriptor	Antihemophilic Factor (Human), Double Viral Inactivation
Indications	Hemophilia A: To temporarily replace missing clotting factor in order to control or prevent bleeding episodes, or to perform emergency and elective surgery. This product contains naturally occurring VWF, but has not been investigated for efficacy in the treatment of VWD and hence is not approved for such usage.
Nominal Dosage Strengths[1]	250 IU, 500 IU, 1000 IU
Contraindications	None known
Viral Removal/ Inactivation	Solvent/detergent treatment; heated in final container at 80°C for 72 hours
Serum Half-Life (Mean)[3]	16.12 hours
Stabilizers/Excipients	Albumin (human), polyethylene glycol, polysorbate 80, glycine, histidine
Rate of Administration[4]	The rate of administration should be adapted to the response of the individual patient, but administration of the entire dose in 5 to10 minutes is generally well tolerated.
Other Administration Considerations[4]	Inspect visually for particulate matter and discoloration prior to administration. Bring the diluent to room temperature prior to reconstitution. Administer within 3 hours after reconstitution.
Diluent Volume	250 IU/500 IU = 5 mL; 1000 IU = 10 mL
Other Package Contents	SWFI, double-ended transfer needle, filter needle, administration set
Storage[4]	Store under refrigeration at 2°C to 8°C (36°F to 46°F). Storage of lyophilized powder at room temperature (up to 25°C [77°F]) for 6 months, such as in home treatment situations, may be done without loss of factor VIII activity. Avoid freezing to prevent possible breakage of the diluent bottle.

Monoclate-P®

Product Name	Monoclate-P®
Manufacturer	CSL Behring
Manufacturer Contact Number	(800) 504-5434
Product Descriptor	Antihemophilic Factor (Human) Factor VIII:C Pasteurized Monoclonal Antibody Purified
Indications	Treatment of hemophilia A, including therapy following minor accidents, temporary corrections of the clotting abnormality prior to surgery, and surgical prophylaxis in severe AHF deficiency by means of a presurgical IV bolus followed by intermittent maintenance doses. Not effective in controlling the bleeding of patients with von Willebrand disease.
Nominal Dosage Strengths[1]	250 IU, 500 IU, 1000 IU, 1500 IU
Contraindications	Known hypersensitivity to mouse protein
Viral Removal/Inactivation	Pasteurization at 60°C for 10 hours
Serum Half-Life (Mean)[3]	17.5 hours
Stabilizers/Excipients	Albumin (human)
Rate of Administration[4]	Administer intravenously at a rate (approximately 2 mL/minute) comfortable to the patient.
Other Administration Considerations[4]	Warm both the diluent and product to room temperature (not above 37°C [98°F]). Inspect visually for particulate matter and discoloration prior to administration. Administer within 3 hours after reconstitution.
Diluent Volume	250 IU = 2.5 mL; 500 IU = 5 mL; 1000 IU/1500 IU = 10 mL
Other Package Contents	Diluent, double-ended needle for reconstitution, vented filter spike for withdrawal, filter needle for withdrawal, winged infusion set and alcohol swabs
Storage[4]	When stored under refrigeration at 2°C to 8°C (36°F to 46°F), the product is stable for the period indicated by the expiration date on its label. Within this period, may be stored at room temperature not to exceed 25°C (77°F), for up to 6 months. Avoid freezing to prevent damage to the diluent container.

Alphanate®

Product Name	Alphanate®
Manufacturer	Grifols
Manufacturer Contact Number	(800) 520-2807
Product Descriptor	Antihemophilic Factor/von Willebrand Factor Complex (Human)
Indications	• Control and prevention of bleeding in patients with factor VIII deficiency due to hemophilia A. • Surgical and/or invasive procedures in adult and pediatric patients with von Willebrand disease (VWD) in whom desmopressin (DDAVP) is either ineffective or contraindicated. Not indicated for patients with severe VWD (Type 3) undergoing major surgery.
Nominal Dosage Strengths[1]	250 IU, 500 IU, 1000 IU, 1500 IU (FVIII) VWF:RCo activity stated on carton and label of each vial
Contraindications	Patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components.
Viral Removal/ Inactivation	Solvent/detergent and 80°C heat treatment
Serum Half-Life (Mean)[3]	21.58 ± 7.79 hours (FVIII); 7.67 ± 3.32 hours (VWF:RCo)
Stabilization	Albumin (human), VWF:Rco
Rate of Administration[4]	Maximum rate not to exceed 10 mL/minute
Other Administration Considerations[4]	Administer at room temperature. After reconstitution, inspect for particulate matter and discoloration prior to administration. Use as soon as possible after reconstitution (within 3 hours).
Diluent Volume	250 IU/500 IU = 5 mL; 1000 IU/1500 IU = 10 mL
Other Package Contents	SWFI diluent vial and Mix2Vial® filter transfer set
Storage[4]	May be stored at up to 25°C (77°F). Do not freeze to prevent damage to the diluent vial.

Humate-P®

Product Name	Humate-P®
Manufacturer	CSL Behring
Manufacturer Contact Number	(800) 504-5434
Product Descriptor	Antihemophilic Factor/von Willebrand Factor Complex (Human)
Indications	Hemophilia A: • Treatment and prevention of bleeding in adults. VWD: In adults and pediatric patients in the: • Treatment of spontaneous and trauma-induced bleeding episodes • Prevention of excessive bleeding during and after surgery.[5] Controlled trials to evaluate prophylactic dosing to prevent spontaneous bleeding have not been conducted in VWD subjects.
Nominal Dosage Strengths[1]	VWF:RCo/FVIII: 600 IU/250 IU; 1200 IU/500 IU[6]
Contraindications	2400 IU/1000 IU
Viral Removal/Inactivation	Heat treatment in aqueous solution at 60°C for 10 hours
Serum Half-Life (Mean)[3]	12.2 hours (range 8.4 to 17.4 hours) (FVIII) 11 hours (range 3.5 to 33.6 hours) (VWF:RCo)
Stabilization	Albumin (human), VWF:Rco
Rate of Administration[4]	Up to 4 mL/minute
Other Administration Considerations[4]	Inspect for particulate matter and discoloration prior to administration. (It is not uncommon for a few small flakes or particles to remain after reconstitution; the Mix2Vial® should remove them.) Ensure that product and diluent are at room temperature prior to reconstitution. Administer within 3 hours after reconstitution.
Diluent Volume	250 IU = 5 mL; 500 IU = 10 mL; 1000 IU = 15 mL
Other Package Contents	SWFI, Mix2Vial® transfer set and two alcohol swabs
Storage[4]	When stored at temperatures up to 25°C (77°F), the product is stable for 24 months up to the expiration date on the label. Do not freeze.

WILATE®

Product Name	WILATE®
Manufacturer	Octapharma USA
Manufacturer Contact Number	(888) 429-4535
Product Descriptor	von Willebrand Factor/Coagulation Factor VIII Complex (Human)
Indications	Children and adults with von Willebrand disease for: • On-demand treatment and control of bleeding episodes • Perioperative management of bleeding. Not indicated for treatment of hemophilia A.
Nominal Dosage Strengths[1]	VWF:RCo/FVIII: 500 IU/500 IU; 1000 IU/1000 IU
Contraindications	Hypersensitivity with known anaphylactic or severe systemic reaction to plasma-derived products, any ingredient in the formulation, or components of the container.
Viral Removal/ Inactivation	Solvent/detergent treatment, terminal dry-heat treatment at 100°C for 120 minutes
Serum Half-Life (Mean)[3]	19.6 ± 6.9 hours (FVIII); 15.8 ± 11.0 hours (VWF:RCo)[7]
Stabilization	VWF:RCo, sucrose, glycine, polysorbate 80
Rate of Administration[4]	2-4 mL/minute
Other Administration Considerations[4]	Warm powder and diluent vials to room temperature. Administer immediately after reconstitution.
Diluent Volume	500 IU = 5 mL; 1000 IU = 10 mL
Other Package Contents	Water for Injection with 0.1% polysorbate 80, Mix2Vial® transfer device, 10 mL syringe, infusion set and 2 alcohol swabs
Storage[4]	Store for up to 36 months at 2°C to 8°C (36°F to 46°F). May be stored at room temperature (maximum of 25°C [77°F]) for up to 6 months. The starting date of room temperature storage should be clearly recorded on the product carton. Once stored at room temperature, the product must not be returned to the refrigerator. The shelf-life then expires after the storage at room temperature, or the expiration date on the product vial, whichever is earliest. Do not freeze.

VONVENDI

Product Name	VONVENDI
Manufacturer	Shire
Manufacturer Contact Number	(800) 828-2088
Product Descriptor	von Willebrand Factor (Recombinant)
Indications	On-demand treatment and control of bleeding episodes in adults diagosed with von Willebrand disease.
Nominal Dosage Strengths[1]	650 IU and 1300 IU VWF:RCo
Contraindications	History of life-threatening hypersensitivity reactions to VONVENDI or its components (mannitol, trehalose, sodium chloride, histidine, Tris, calcium chloride, polysorbate 80, and hamster or mouse proteins)
Viral Removal/ Inactivation	-
Serum Half-Life (Mean)[3]	See full prescribing information
Stabilizers/Excipients	Tri-sodium citrate-dihydrate, glycine, mannitol, trehalose-dihydrate, polysorbate 80
Rate of Administration[4]	Maximum infusion rate of 4 mL/minute
Other Administration Considerations[4]	Inspect after filtration/withdrawal into the syringe for discoloration and particulate matter prior to administration. The solution should be clear or slightly opalescent in appearance. Do not administer if particulate matter, discoloration or cloudiness is observed. Administer immediately after reconstitution; if not, store at room temperature and discard after 3 hours.
Diluent Volume	5 mL (650 IU) and 10 mL (1300 IU)
Other Package Contents	SWFI, Mix2Vial® reconstitution device
Storage[4]	Store at 2°C to 8°C (36°F to 46°F). Do not freeze. May store at room temperature up to 30°C (86°F) for a period of up to 12 months. After storing at room temperature, do not return the product to the refrigerator.

Product Name	Stimate®
Manufacturer	CSL Behring
Manufacturer Contact Number	(800) 504-5434
Product Descriptor	Desmopressin acetate
Indications	Hemophilia A with factor VIII coagulant activity levels greater than 5%. Mild to moderate classic von Willebrand disease (Type 1) with factor VIII levels greater than 5%; will also stop bleeding in patients with episodes of spontaneous or trauma-induced injuries such as hemarthroses, intramuscular hematomas, mucosal bleeding or menorrhagia).
Dosage Strengths	1.5 mg/mL
Contraindications	None
Serum Half-Life (Mean)	3.3 to 3.5 hours
Dosage and Administration[4]	Administer by nasl insufflation, one spray per nostril, to provide a total dose of 300 mcg. In patients weighing less than 50 kg, 150 mcg administered as single spray provided the expected effect o factor VIII coagulant activity, factor VIII ristocetin cofactor activity and skin bleeding time.
How Supplied	2.5 mL bottle with spray pump capable of delivering 25 sprays of 150 mcg
Storage	Store at room temperature not to exceed 25°C (77°F) for the period indicated by the expiration date on the label. Discard six months after being opened. tore bottle in an upright position.

AlphaNine® S/D

Product Name	AlphaNine® S/D
Manufacturer	Grifols
Manufacturer Contact Number	(800) 520-2807
Product Descriptor	Coagulation Factor IX (Human)
Indications	Prevention and control of bleeding in patients with factor IX deficiency due to hemophilia B.[9]
Dosage Strengths	500 IU, 1000 IU, 1500 IU
Contraindications	None known
Viral Removal/ Inactivation	Solvent/detergent, nanofiltration
Serum Half-Life (Mean)	~21 hours
Stabilizers/Excipients	Dextrose and polysorbate 80
Rate of Administration[4]	Not to exceed 10 mL/minute.
Other Administration Considerations[4]	Warm diluent and concentrate vial to at least room temperature before reconstitution (but not above 37˚C). Inspect for particulate matter and discoloration prior to administration. Use reconstituted product within 3 hours of reconstitution.
Diluent Volume	10 mL
Other Package Contents	10 mL Sterile Water for Injection, USP and Mix2Vial® filter transfer set
Storage[4]	Store at temperatures between 2°C to 8°C (36°F to 46°F). Do not freeze to prevent damage to the diluent vial. May be stored at room temperature not to exceed 30°C (86°F) for 1 month.

Mononine®

Product Name	Mononine®
Manufacturer	CSL Behring
Manufacturer Contact Number	(800) 504-5434
Product Descriptor	Coagulation Factor IX (Human), Monoclonal Antibody Purified
Indications	Prevention and control of bleeding in factor IX deficiency, also known as hemophilia B or Christmas disease.[10]
Dosage Strengths	500 IU, 1000 IU
Contraindications	Known hypersensitivity to mouse protein
Viral Removal/ Inactivation	Monoclonal antibody immunoaffinity chromatography, sodium thiocyanate and ultrafiltration
Serum Half-Life (Mean)	~22.6 hours
Stabilization	Histidine, mannitol and polysorbate 80
Rate of Administration[4]	The rate of administration should be determined by the response and comfort of the patient; intravenous dosage administration rates of up to 225 IU/minute have been regularly tolerated without incident. When reconstituted as directed, i.e., to approximately 100 IU/mL, Mononine should be administered at a rate of approximately 2.0 mL per minute.
Other Administration Considerations[4]	Inspect for particulate matter and discoloration prior to administration. Use reconstituted product within 3 hours of reconstitution. Use of plastic disposable syringes is recommended.
Diluent Volume	500 IU = 5 mL; 1000 IU = 10 mL
Other Package Contents	Sterile Water for Injection USP diluent, double-ended needle for reconstitution, vented filter spike for withdrawal, winged infusion set and alcohol swabs
Storage[4]	When stored at refrigerator temperature of 2°C to 8°C (36°F to 46°F), Mononine is stable for the period indicated by the expiration date on its label. Within this period, Mononine may be stored at room temperature not to exceed 25°C (77°F), for up to 1 month. Avoid freezing, which may damage container for the diluent.

BeneFIX®

Product Name	BeneFIX®
Manufacturer	Pfizer
Manufacturer Contact Number	(800) 438-1985
Product Descriptor	Coagulation Factor IX (Recombinant)
Indications	• Control and prevention of bleeding episodes in adult and pediatric patients with hemophilia B (congenital factor IX deficiency or Christmas disease). • Peri-operative management of adult and pediatric patients with hemophilia B.[11]
Dosage Strengths	250 IU, 500 IU, 1000 IU, 2000 IU, 3000 IU
Contraindications	Patients who have manifested life-threatening, immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including hamster protein
Viral Removal/ Inactivation	Nanofiltration
Serum Half-Life (Mean)	~18.8 hours ± 5.4 hours; range 11 to 36 hours
Stabilizers/Excipients	L-histidine, glycine, sucrose and polysorbate 80
Rate of Administration[4]	Administer over a period of several minutes; adapt rate to the comfort level of each individual patient.
Other Administration Considerations[4]	Inspect for particulate matter and discoloration prior to administration. Reconstituted product should appear clear and colorless. Administer at room temperature. Use product within 3 hours of reconstitution. If red blood cell agglutination is observed in the tubing or syringe, discard all materials (tubing, syringe and BeneFIX solution) and resume administration with a new package.
Diluent Volume	5 mL for all dosage strengths
Other Package Contents	Sterile prefilled diluent syringe, vial adapter reconstitution device, sterile infusion set, 2 alcohol swabs, 1 bandage and 1 gauze pad.
Storage[4]	Product may be labeled for either room temperature storage or refrigeration; for storage and handling information refer to full prescribing information accompanying product. Do not freeze to prevent damage to the diluent syringe.

Product Name	IXINITY®
Manufacturer	Aptevo BioTherapeutics
Manufacturer Contact Number	(855) 494-6489
Product Descriptor	Coagulation Factor IX (Recombinant)
Indications	In adults and children ≥ 12 years of age with hemophilia B for: • Control and prevention of bleeding episodes • Perioperative management Not indicated for induction of immune tolerance in patients with hemophilia B.
Dosage Strengths	250 IU, 500 IU, 1000 IU, 1500 IU, 2000 IU, or 3000 IU
Contraindications	Patients with known hypersensitivity to IXINITY or its excipients, including hamster protein.
Viral Removal/ Inactivation	Solvent/detergent treatment, chromatography, nanofiltration
Serum Half-Life (Mean)	24 ± 7 hours
Stabilizers/Excipients	Histidine, mannitol, trehalose dehydrate, sodium chloride, polysorbate 80
Rate of Administration[4]	Not exceeding 10 mL per minute; adapt infusion rate to the comfort level of each patient.
Other Administration Considerations[4]	Inspect reconstituted product for particulate matter and discoloration prior to administration; the solution should be clear and colorless without visible particles. Infuse within 3 hours. Do not refrigerate after reconstitution.
Diluent Volume	5 mL
Other Package Contents	10 mL syringe pre-filled with 5 mL of SWFI with plunger rod attached, vial adapter with filter, and sterile 20 mL LUER-LOK Administration Syringe.
Storage[4]	Store at 2 to 25°C (36 to 77°F). Do not freeze.

RIXUBIS

Product Name	RIXUBIS
Manufacturer	Shire
Manufacturer Contact Number	(800) 828-2088
Product Descriptor	Coagulation Factor IX (Recombinant)
Indications	In adults and children with hemophilia B: • Control and prevention of bleeding episodes • Perioperative management • Routine prophylaxis
Dosage Strengths	250 IU, 500 IU, 1000 IU, 2000 IU, 3000 IU
Contraindications	• Known hypersensitivity to RIXUBIS or its excipients including hamster protein • Disseminated intravascular coagulation (DIC) • Signs of fibrinolysis
Viral Removal/ Inactivation	Solvent/detergent, nanofiltration
Serum Half-Life (Mean)	26.7 hours ± 9.6 hours
Stabilizers/Excipients	L-histidine, sodium chloride, calcium chloride, mannitol, sucrose and polysorbate 80
Rate of Administration[4]	Maximum infusion rate of 10 mL/minute
Other Administration Considerations[4]	Inspect parenteral drug products for particulate matter and discoloration prior to administration. The solution should be clear and colorless in appearance.
Diluent Volume	5 mL
Other Package Contents	Sterile Water for Injection and a BAXJECT II transfer device.
Storage[4]	Store at refrigerator temperature 2°C to 8°C (36°F to 46°F) for up to 24 months. Do not freeze. May store at room temperature not to exceed 30°C (86°F) for up to 12 months within the 24 month time period.

Product Name	ALPROLIX®
Manufacturer	Biogen
Manufacturer Contact Number	(855) 692-5776
Product Descriptor	Coagulation Factor IX (Recombinant), Fc Fusion Protein
Indications	In adults and children with hemophilia B: • Control and prevention of bleeding episodes • Perioperative management • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes
Dosage Strengths	500 IU, 1000 IU, 2000 IU, 3000 IU
Contraindications	Individuals who have a known history of hypersensitivity reactions, including anaphylaxis, to the product or its excipients.
Viral Removal/Inactivation	Nanofiltration, column chromatography purification
Serum Half-Life (Mean)	66.40 to 86.52 hours (varies by age range; see prescribing information)
Stabilizers/Excipients	Mannitol, L-histidine, polysorbate-20 and sucrose
Rate of Administration[4]	Should be determined by the patient's comfort level, and no faster than 10 mL per minute.
Other Administration Considerations[4]	Administer within 3 hours of reconstitution. Do not refrigerate after reconstitution. Keep away from direct sunlight. Inspect for particulate matter and discoloration prior to administration. Do not administer in the same tubing or container with other medicinal products.
Diluent Volume	5 mL for all dosage strengths
Other Package Contents	Prefilled syringe containing 5 mL diluent (sealed with plunger stopper and tip-cap) and a sterile vial adapter (reconstitution device).
Storage[4]	Store at 2°C to 8°C (36°F to 46°F). If stored at room temperature, do not exceed 30°C (86°F) for a single 6 month period. Do not place product back into refrigeration after warming to room temperature. Reconstituted product may be stored at room temperature, not to exceed 30°C (86°F) for no longer than 3 hours. Do not freeze to prevent damage to diluent syringe.

IDELVION®

Product Name	IDELVION®
Manufacturer	CSL Behring
Manufacturer Contact Number	(800) 504-5434
Product Descriptor	Coagulation Factor IX (Recombinant), Albumin Fusion Protein
Indications	In children and adults with hemophilia B: • On-demand control and prevention of bleeding episodes • Perioperative management of bleeding • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes
Dosage Strengths	250 IU, 500 IU, 1000 IU, 2000 IU
Contraindications	History of life-threatening hypersensitivity reactions to IDELVION, or its components, including hamster proteins.
Viral Removal/ Inactivation	Solvent/detergent, nanofiltration
Serum Half-Life (Mean)	104 hours (at a dose of 50 or 75 IU/kg)
Stabilizers/Excipients	Sodium citrate, polysorbate 80, mannitol and sucrose
Rate of Administration[4]	Adapt the infusion rate to the comfort level of each patient, not exceeding 10 mL per minute.
Other Administration Considerations[4]	Visually inspect final solution for particulate matter and discoloration; do not administer if either is observed. Administer at room temperature and within 4 hours of reconstitution. Do not refrigerate.
Diluent Volume	250 IU/500 IU/1000 IU = 2.5 mL; 2000 IU = 5 mL
Other Package Contents	Sterile Water for Injection, USP, Mix2Vial® filter transfer set, one sterile alcohol swab
Storage[4]	Store at 2°C to 25°C (36°F to 77°F). Do not freeze.

FEIBA

Product Name	FEIBA
Manufacturer	Shire
Manufacturer Contact Number	(800) 828-2088
Product Descriptor	Anti-Inhibitor Coagulant Complex
Indications	In hemophilia A and B patients with inhibitors: • Control and prevention of bleeding episodes • Perioperative management • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes.[12] Not indicated for the treatment of bleeding episodes resulting from coagulation factor deficiencies in the absence of inhibitors to factor VIII or factor IX.
Dosage Strengths	500, 1000 and 2500 units[13]
Contraindications	• Known anaphylactic or severe hypersensitivity reactions to FEIBA or any of its components, including factors of the kinin generating system. • Disseminated intravascular coagulation (DIC). • Acute thrombosis or embolism (including MI).
Viral Removal/ Inactivation	35 nm nanofiltration and vapor heat treatment
Serum Half-Life (Mean)	Not stated in prescribing information
Stabilizers/Excipients	Trisodium citrate
Rate of Administration[4]	Must not exceed 2 units per kg of body weight per minute.
Other Administration Considerations[4]	Inspect visually for particulate matter and discoloration prior to administration. Administer within 3 hours after reconstitution. Do not refrigerate after reconstitution. Use plastic luer lock syringes because protein such as FEIBA tends to stick to the surface of all-glass syringes.
Diluent Volume	20 mL or 50 mL (in accordance with product potency)
Other Package Contents	Sterile Water for Injection, USP, and a BAXJECT II Hi-Flow Needleless Transfer Device
Storage[4]	Store at room temperature, not to exceed 25˚C (77˚F).

NovoSeven® RT

Product Name	NovoSeven® RT
Manufacturer	Novo Nordisk
Manufacturer Contact Number	(877) 668-6777
Product Descriptor	Coagulation Factor VIIa (Recombinant) Room Temperature-Stable
Indications	• Treatment of bleeding episodes in hemophilia A and B patients with inhibitors to factor VIII or factor IX and in patients with acquired hemophilia • Prevention of bleeding in surgical interventions or invasive procedures in hemophilia A or B patients with inhibitors to factor VIII or factor IX and in patients with acquired hemophilia • Treatment of bleeding episodes in patients with congenital factor VII (FVII) deficiency • Prevention of bleeding in surgical interventions or invasive procedures in patients with congenital FVII deficiency
Dosage Strengths	1 mg (1000 mcg), 2 mg (2000 mcg), 5 mg (5000 mcg) and 8 mg (8000 mcg)
Contraindications	None
Viral Removal/ Inactivation	NovoSeven RT purification process
Serum Half-Life (Mean)	Hemophilia A or B: 2.3 hours (range 1.7 – 2.7). Congenital factor VII deficiency: 2.82 to 3.11 hours.
Stabilizers/Excipients	Mannitol, L-histidine, sucrose, polysorbate-80 and calcium chloride dihydrate
Rate of Administration[4]	Refer to full prescribing information; administer as a slow bolus injection over 2 to 5 minutes, depending on the dose administered.
Other Administration Considerations[4]	Administration should take place within 3 hours after reconstitution. Inspect visually for particulate matter and discoloration prior to administration. Do not mix with infusion solutions. If line needs to be flushed before or after NovoSeven RT administration, use 0.9% Sodium Chloride Injection, USP.
Diluent Volume	10 mmol solution of L-histidine in water for injection
Other Package Contents	NovoSeven RT: 1 vial of histidine diluent NovoSeven RT with MixPro®: [4] prefilled histidine diluent syringewith sterile vial adapter
Storage[4]	Prior to reconstitution, store NovoSeven RT powder and histidine diluent between 2°C to 25°C (36°F to 77°F). Do not freeze. Store protected from light. After reconstitution, NovoSeven RT may be stored either at room temperature or refrigerated for up to 3 hours. Do not freeze reconstituted product or store in syringes.

Product Name	OBIZUR
Manufacturer	Shire
Manufacturer Contact Number	(800) 828-2088
Product Descriptor	Antihemophilic Factor (Recombinant), Porcine Sequence
Indications	Treatment of bleeding episodes in adults with acquired hemophilia A.[14]
Dosage Strengths	500 units
Contraindications	Do not use in patients who have had life-threatening hypersensitivity reactions to OBIZUR or its components, including hamster protein.
Viral Removal/ Inactivation	Solvent/detergent, nanofiltration
Serum Half-Life (Mean)	Variable[4]
Stabilizers/Excipients	Sodium chloride, Tris-base, Tris-HCl, tri-sodium citrate dehydrate, calcium chloride dehydrate, sucrose, and polysorbate 80
Rate of Administration[4]	1 to 2 mL/minute
Other Administration Considerations[4]	Inspect for particulate matter and discoloration prior to administration. The solution should be clear and colorless. Do not administer in the same tubing or container with other products for infusion. Use OBIZUR within 3 hours after reconstitution when stored at room temperature.
Diluent Volume	1 mL
Other Package Contents	Pre-filled syringe with Sterile Water for Injection, vial adaptor with filter
Storage[4]	Store OBIZUR at refrigeration temperature of 2°C to 8°C (36°F to 46°F). Store vials in the original package to protect from light. Do not freeze.

BEBULIN

Product Name	BEBULIN
Manufacturer	Shire
Manufacturer Contact Number	(800) 828-2088
Product Descriptor	Factor IX Complex, Nanofiltered and Vapor Heated
Indications	Prevention and control of hemorrhagic episodes in hemophilia B patients.[15]
Dosage Strengths	Factor IX activity in IUs is stated on the label of each vial
Contraindications	Known history of hypersensitivity reactions to the product. Known allergy to heparin. Known history of heparin-induced thrombocytopenia.
Viral Removal/ Inactivation	Nanofiltration and vapor heat treatment
Serum Half-Life (Mean)	19.97 hours ± 8.24 hours
Stabilizers/Excipients	Heparin added
Rate of Administration[4]	Administer at a rate comfortable to patient. Maximum rate 2 mL/minute.
Other Administration Considerations[4]	Inspect for particulate matter and discoloration prior to administration. Administer at room temperature. Do not refrigerate after reconstitution. Use reconstituted product within 3 hours of reconstitution.
Diluent Volume	20 mL for all dosage strengths
Other Package Contents	Sterile Water for Injection, USP diluent, double-ended needle and filter needle for reconstitution and withdrawal
Storage[4]	Store at refrigerator temperature, 2°C to 8°C (36°F to 46°F). Do not freeze.

Product Name	Profilnine®
Manufacturer	Grifols
Manufacturer Contact Number	(800) 520-2807
Product Descriptor	Factor IX Complex, Solvent/Detergent Treated/Nanofiltered
Indications	Prevention and control of bleeding in patients with factor IX deficiency (hemophilia B).
Dosage Strengths	500 IU, 1000 IU, 1500 IU
Contraindications	None known
Viral Removal/ Inactivation	Solvent detergent
Serum Half-Life (Mean)	~24.68 hours ± 8.29 hours
Stabilizers/Excipients	Polysorbate 80
Rate of Administration[4]	Not to exceed 10 mL/minute.
Other Administration Considerations[4]	Inspect visually for particulate matter and discoloration prior to administration. Administer at room temperature. Ensure that concentrate and diluent are at room temperature (but not above 37°C) before reconstitution. While stable for 3 ours after reconstitution, prompt administration is recommended.
Diluent Volume	500 IU = 5 mL; 1000 IU = 10 mL; 1500 IU = 10 mL
Other Package Contents	Sterile Water for Injection, USP and Mix2Vial® filter transfer set
Storage[4]	Stable for 3 years, up to the expiration date printed on its label, provided that the storage temperature does not exceed 25°C (77°F). Do not freeze.

Kcentra®

Product Name	Kcentra®
Manufacturer	CSL Behring
Manufacturer Contact Number	(800) 504-5434
Product Descriptor	Prothrombin Complex Concentrate (Human)
Indications	Urgent reversal of acquired coagulation factor deficiency induced by Vitamin K antagonist (VKA, e.g., warfarin) therapy in adult patients with: • Acute major bleeding or • Need for an urgent surgery/invasive procedure
Dosage Strengths	500 IU, 1000 IU
Contraindications	• Known anaphylactic or severe systemic reactions to Kcentra or any components in Kcentra including heparin, Factors II, VII, IX, X, Proteins C and S, Antithrombin III and human albumin. • Disseminated intravascular coagulation. • Known heparin-induced thrombocytopenia (Kcentra contains heparin).
Viral Removal/ Inactivation	Ion exchange chromatography, heat treatment at 60°C for 10 hours, precipitation, calcium phosphate adsorption, nanofiltration
Serum Half-Life (Mean)	See full prescribing information
Stabilization	Human antithrombin III, heparin, human albumin, sodium chloride, sodium citrate
Rate of Administration[4]	Administer by intravenous infusion at a rate of 0.12 mL/kg/min (~3 units/kg/min), up to a maximum rate of 8.4 mL/min (~210 units/min).
Other Administration Considerations[4]	Visually inspect for particulate matter and discoloration prior to administration. Reconstituted solution should be colorless, clear to slightly opalescent, and free from visible particles. Administer at room temperature; begin promptly or within 4 hours.
Diluent Volume	500 units: 20 mL; 1000 units: 40 mL
Other Package Contents	Sterile Water for Injection, Mix2Vial® filter transfer set, alcohol swab
Storage[4]	Store between 2°C to 25°C (36°F to 77°F), this includes room temperature, not to exceed 25°C (77°F). Do not freeze. Stable for 36 months from the date of manufacture, up to the expiration date on the carton and vial labels. Reconstituted product can be stored at 2°C to 25°C. If cooled, the solution should be warmed to 20°C to 25°C prior to administration. Do not freeze the reconstituted product.

COAGADEX®[8]

Product Name	COAGADEX®
Manufacturer	Bio Products Laboratory
Manufacturer Contact Number	(866) 398-0825
Product Descriptor	Coagulation Factor X (Human)
Indications	In adults and children (aged 12 years and above) with hereditary Factor X deficiency: • On-demand treatment and control of bleeding episodes • Perioperative management of bleeding in patients with mild hereditary Factor X deficiency
Dosage Strengths	250 IU, 500 IU
Contraindications	Do not use in patients who have had life-threatening hypersensitivity reactions to COAGADEX or any of the components.
Viral Removal/ Inactivation	Solvent/detergent, nanofiltration, terminal dry heat
Serum Half-Life (Mean)	30.3 hours
Stabilizers/Excipients	Chloride, phosphate, citrate and sodium compounds, sucrose
Rate of Administration[4]	10 mL/min (no more than 20 mL/min)
Other Administration Considerations[4]	Visually inspect final solution for particulate matter and discoloration prior to administration; do not use if these are observed. Use reconstituted product immediately (within one hour) after reconstitution; do not store reconstituted product.
Diluent Volume	250 IU = 2.5 mL; 500 IU = 5 mL
Other Package Contents	Sterile Water for Injection, Mix2Vial® transfer device
Storage[4]	Store in a refrigerator or at room temperature (36°F to 86°F). Do not freeze.

Corifact®

Product Name	Corifact®
Manufacturer	CSL Behring
Manufacturer Contact Number	(800) 504-5434
Product Descriptor	Factor XIII Concentrate (Human)
Indications	Adult and pediatric patients with congenital Factor XIII deficiency for: • Routine prophylactic treatment • Perioperative management of surgical bleeding
Dosage Strengths	1000-1600 IU
Contraindications	Do not use in patients with anaphylactic or severe systemic reactions to human plasma-derived products.
Viral Removal/ Inactivation	Heat-treatment, nanofiltration, ion exchange chromatography
Serum Half-Life (Mean)	7.1 ± 2.74 days
Stabilizers/Excipients	Human albumin, glucose, sodium chloride
Rate of Administration[4]	Administer at a rate not to exceed 4 mL/minute
Other Administration Considerations[4]	Inspect for particulate matter and discoloration prior to administration. Must be used within 4 hours after reconstitution. Do not refrigerate or freeze the reconstituted solution.
Diluent Volume	20 mL
Other Package Contents	Sterile Water for Injection, USP, Mix2Vial® filter transfer set, alcohol swab
Storage[4]	Refrigerate at 2°C to 8°C (36°F to 46°F). Do not freeze. May be stored at room temperature not to exceed 25°C (77°F) for up to 6 months.

Product Name	Tretten®
Manufacturer	Novo Nordisk
Manufacturer Contact Number	(877) 668-6777
Product Descriptor	Coagulation Factor XIII A-Subunit (Recombinant)
Indications	Routine prophylaxis of bleeding in patients with cogenital Factor XIII A-subunit deficiency. Not for use in patients with congenital factor XIII B-subunit deficiency.
Dosage Strengths	2000-3125 IU
Contraindications	Hypersensitivity to the active substance or to any of the excipients.
Viral Removal/ Inactivation	–
Serum Half-Life (Mean)	5.1 ± 2.6 days
Stabilizers/Excipients	Sodium chloride, sucrose, polysorbate 20, L-histidine
Rate of Administration[4]	Not to exceed 1-2 mL/minute
Other Administration Considerations[4]	Inspect reconstituted TRETTEN visually for particulate matter anad discoloration; do not administer if either is observed. Do not administer with other infusion solutions. Do not administer as drip. Use reconstituted TRETTEN immediately after it is dissolved (within 3 hours).
Diluent Volume	3.2 mL
Other Package Contents	Sterile Water for Injection
Storage[4]	Store refrigerated at 2°C to 8°C (36°F to 46°F) prior to reconstitution. Do not freeze. Store protected from light.

RiaSTAP®

Product Name	RiaSTAP®
Manufacturer	CSL Behring
Manufacturer Contact Number	(800) 504-5434
Product Descriptor	Fibrinogen Concentrate (Human)
Indications	Treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia.
Dosage Strengths	900-1300 mg
Contraindications	Known anaphylactic or severe systemic reactions to human plasma-derived products.
Viral Removal/ Inactivation	Cryoprecipitation, heat treatment, glycine precipitation steps
Serum Half-Life (Mean)	78.7 ± 18.13 hours
Stabilizers/Excipients	Human albumin, L-arginine hydrochloride, sodium chloride, sodium citrate
Rate of Administration[4]	Injection rate should not exceed 5 mL per minute.
Other Administration Considerations[4]	Inspect for particulate matter and discoloration; do not administer is the solution is cloudy or contains particulates. Discard partially used vials. Administer at room temperature. When stored at 20°C to 25°C, product is stable for 8 hours; administer within this time period.
Diluent Volume	50 mL
Other Package Contents	–
Storage[4]	When stored at temperatures of 2°C to 25°C (36°F-77°F), RiaSTAP is stable for the period indicated by the expiration date on the carton and vial label (up to 60 months). Do not use RiaSTAP beyond the expiration date. Keep RiaSTAP in its original carton until ready to use. Do not freeze. Protect from light.

Footnotes

KEY

AHF: antihemophilic factor
AICC: anti-inhibitor coagulant complex
DIC: disseminated intravascular coagulation
IU: international unit
FVIII: factor VIII
MI: myocardial infarction
RCo: Ristocetin cofactor
rFVIII: recombinant factor VIII
SWFI: Sterile Water for Injection USP
VWD: von Willebrand disease
VWF: von Willebrand factor

NOTES

1. See full prescribing information for actual dosage ranges corresponding to each nominal product strength.
2. Also available in 4 intermediate potencies: 375 IU, 750 IU, 1700 IU and 2500 IU.
3. All values are for adults. Serum half-life may be shorter in children and adolescents; see full prescribing information.
4. Refer to full prescribing information.
5. This applies to patients with severe VWD as well as patients with mild to moderate VWD where the use of desmopressin is known or suspected to be inadequate.
6. Actual potency in international units (IU) is imprinted on the label and the unit carton.
7. Half-life varies by type of VWD; see full prescribing information.
8. FFF does not currently supply this product.
9. AlphaNine SD contains low, non-therapeutic levels of factors II, VII and X, and therefore is not indicated for the treatment of factor II, VII or X deficiencies. Not indicated for the reversal of coumarin anticoagulant-induced hemorrhage, nor the treatment of hemophilia A patients with inhibitors to factor VIII.
10. Mononine is not indicated (1) in the treatment or prophylaxis of hemophilia A patients with inhibitors to factor VIII, (2) as replacement therapy of factors II, VII or X, or (3) in the treatment or reversal of coumarin-induced anticoagulation or in a hemorrhagic state caused by hepatitis-induced lack of production of liver-dependent coagulation factors.
11. BeneFIX is not indicated for reversal of coumarin-induced anticoagulation or treatment of (1) other factor deficiencies, (2) hemophilia A patients with inhibitors to factor VIII, or (3) bleeding due to low levels of liver-dependent coagulation factors.
12. Clinical experience suggests that patients with factor VIII inhibitors less than 5 Bethesda Units (BU) may be successfully treated with anti-hemophilic factor. Patients with titers ranging between 5 and 10 BU may either be treated with anti-hemophilic factor or FEIBA NF. Cases with factor VIII inhibitor titers greater than 10 BU have generally been refractory to treatment with anti-hemophilic factor.
13. Actual number of units of factor VIII inhibitor bypassing activity is stated on the label of each vial.
14. Limitations of use: (1) Safety and efficacy of OBIZUR has not been established in patients with a baseline anti-porcine factor VIII inhibitor titer of greater than 20 BU; and (2) OBIZUR is not indicated for the treatment of congenital hemophilia A or von Willebrand disease.
15. Bebulin is not indicated for the treatment of factor VII deficiency. No clinical studies have been conducted to show benefit from product for treating deficiencies other than factor IX deficiency.

SOURCES

The information presented in this guide is not meant to serve as a guideline for patient management. Any procedures, medications or other courses of diagnosis or treatment discussed or suggested in this guide should not be used by clinicians without full evaluation of their patients' conditions and possible contraindications or dangers in use, review of any applicable manufacturer's product information, and comparison with recommendations of other authorities.

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