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CONTENTS

ADVATE®

Intravenous

Product Name	ADVATE®
Manufacturer	Takeda
Manufacturer Contact Number	(800) 828-2088
Product Descriptor	Antihemophilic Factor (Recombinant)
Indications	In adults and children with hemophilia A for: • Control and prevention of bleeding episodes • Perioperative management • 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, 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]	12.0 ± 4.2 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 within 3 hours of reconstitution.
Diluent Volume	2 mL (250 through 1500 IU dosages) or 5 mL (2000 through 4000 IU dosages)
Other Package Contents	Sterile Water for Injection USP (2 mL or 5 mL) and BAXJECT III reconstitution system, 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. After storage at room temperature, the product must not be returned to the refrigerator. Do not freeze.

KOVALTRY®

Intravenous

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.
Viral Clearance/ Inactivation	Detergent treatment, 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®

Intravenous

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: • 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, 1500 IU, 2000 IU, 3000 IU
Contraindications	Patients who have had life-threatening hypersensitivity reactions, including anaphylaxis, to Novoeight or its components (including hamster proteins).
Viral Removal/ Inactivation	Detergent treatment, 20-nm filtration
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. Do not administer Novoeight in the same tubing or container with other medicinal products.
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 until the expiration date stated on the carton. Within the 30-month period, Novoeight may also be kept at room temperature (RT) up to 86°F (≤30°C) for no longer than 12 months, or RT up to 104°F (≤40°C) for no longer than 3 months.

NUWIQ®

Intravenous

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 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, 2500 IU, 3000 IU, 4000 IU
Contraindications	History of life-threatening reactions, including anaphylaxis, to the product or its components.
Viral Removal/ Inactivation	Solvent/detergent treatment, nanofiltration
Serum Half-Life (Mean)[3]	17.1 ± 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. Use reconstituted solution immediately or within 3 hours after reconstitution. Do not administer in the same tubing or container as other medications.
Diluent Volume	2.5 mL
Other Package Contents	Pre-filled syringe with Sterile Water for Injection USP, 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™

Intravenous

Product Name	RECOMBINATE™
Manufacturer	Takeda
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]	250 IU, 500 IU, 1000 IU, 1500 IU, 2000 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
Other Administration Considerations[4]	Inspect 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	Sterile Water for Injection USP 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®

Intravenous

Product Name	XYNTHA® and XYNTHA® SOLOFUSE®
Manufacturer	Pfizer
Manufacturer Contact Number	(800) 438-1985
Product Descriptor	Antihemophilic Factor (Recombinant)
Indications	In adults and children with hemophilia A for: • Control and prevention of bleeding episodes • Perioperative management • 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 (Xyntha Solofuse only)
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
Stabilizers/Excipients	Sucrose, polysorbate 80, L-histidine, calcium chloride, and sodium 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]	Allow vial and prefilled diluent syringe or Xyntha Solofuse Kit to reach room temperature. Inspect visually for particulate matter before administration. Should be administered within 3 hours after reconstitution.
Diluent Volume	4 mL
Other Package Contents	Either (1) Prefilled diluent syringe containing 4 mL 0.9% NaCl with plunger rod for assembly, vial adapter, sterile infusion set, two alcohol swabs, one bandage and one gauze pad; or (2) Xyntha Solofuse kit[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.

ADYNOVATE®

Intravenous

Product Name	ADYNOVATE®
Manufacturer	Takeda
Manufacturer Contact Number	(800) 828-2088
Product Descriptor	Antihemophilic Factor (Recombinant), PEGylated
Indications	In children and adults with hemophilia A for: • On-demand treatment and control of bleeding episodes • Perioperative management • 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, 750 IU, 1000 IU, 1500 IU, 2000 IU, 3000 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]	Administer over a period less than or equal to 5 minutes (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. Administer as soon as possible, but no later than 3 hours after reconstitution.
Diluent Volume	2 mL or 5 mL
Other Package Contents	Sterile Water for Injection USP in BAXJECT III reconstitution system, one Terumo Microbore infusion set (2 mL only)
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 3 months. After storing at room temperature, do not return the product to the refrigerator.

AFSTYLA®

Intravenous

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, 1500 IU, 2000 IU, 2500 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
Stabilizers/Excipients	L-histidine, polysorbate 80, calcium chloride, sodium chloride, sucrose
Rate of Administration[4]	Do not exceed infusion rate of 10 mL per minute. The rate of administration should be determined by the patient's comfort level.
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; 1500 IU/2000 IU/2500 IU/3000 IU = 5 mL
Other Package Contents	Sterile Water for Injection USP, 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.

ALTUVIIIO®

Intravenous

Product Name	ALTUVIIIO®
Manufacturer	Sanofi
Manufacturer Contact Number	800-633-1610
Product Descriptor	Antihemophilic factor (recombinant), (Fc-VWF-XTEN fusion protein-ehtl)
Indications	In adults and children with hemophilia A for: • Routine prophylaxis to reduce the frequency of bleeding episodes • On-demand treatment & control of bleeding episodes • Perioperative management of bleeding. Not indicated for the treatment of von Willebrand disease
Dosage Strengths	250, 500, 750, 1000, 2000, 3000, or 4000 IU
Contraindications	Do not use in patients who have had severe hypersensitivity reactions, including anaphylaxis, to ALTUVIIIO or excipients of ALTUVIIIO.
Viral Removal/ Inactivation	Detergent treatment, nanofiltration
Serum Half-Life (Mean)[3]	Varies by age range; see prescribing information.
Stabilizers/Excipients	Arginine hydrochloride, calcium chloride dihydrate, histidine, polysorbate 80, and sucrose.
Rate of Administration[4]	Slowly over 1 to 10 minutes, based on the patient's comfort level.
Other Administration Considerations[4]	Inspect visually for particulate matter and discoloration prior to administration. Do not administer reconstituted ALTUVIIIO in the same tubing or container with other medications.
Diluent Volume	3 mL
Other Package Contents	A prefilled syringe with 3 mL sterile water for injection, and a sterile vial adapter (reconstitution device).
Storage[4]	Store refrigerated 2°C to 8°C (36°F to 46°F) up to 48 months or at room temperature [not to exceed 30°C (86°F)], for a single period up to 6 months. Once stored in refrigerator, use or discard before the end of this 6-month period; do not return the product to the refrigerator.

ELOCTATE®

Intravenous

Product Name	ELOCTATE®
Manufacturer	Sanofi
Manufacturer Contact Number	(800) 633-1610
Product Descriptor	Antihemophilic Factor (Recombinant), Fc Fusion Protein
Indications	In adults and children with hemophilia A for: • 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, 750 IU, 1000 IU, 1500 IU, 2000 IU, 3000 IU, 4000 IU, 5000 IU, 6000 IU
Contraindications	Patients who have had life-threatening hypersensitivity reactions to ELOCTATE or its excipients (sucrose, sodium chloride, L-histidine, calcium chloride, polysorbate 20).
Viral Removal/ Inactivation	Detergent treatment, 15 nm filtration
Serum Half-Life (Mean)[3]	19.7 ± 2.3 hours
Stabilizers/Excipients	Sucrose, sodium chloride, 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]	Allow the vial of ELOCTATE and prefilled syringe to reach room temperature before use. Administer within 3 hours of reconstitution. 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 Sterile Water for Injection USP and a sterile vial adapter (reconstitution device)
Storage[4]	Store the ELOCTATE® package at 2 to 8°C (36 to 46°F). May also be stored at room temperature (up to 25°C or 77°F) for up to 6 months. After storage at room temperature, do not return the product to the refrigerator.

JIVI®[8]

Intravenous

Product Name	JIVI®
Manufacturer	Bayer
Manufacturer Contact Number	(800) 288-8374
Product Descriptor	Antihemophilic Factor (Recombinant), PEGylated-aucl
Indications	In previously treated adults and adolescents (12 years of age and older) with hemophilia A for: • On-demand treatment and control of bleeding episodes • Perioperative management of bleeding • Routine prophylaxis to reduce the frequency of bleeding episodes Jivi is not indicated for use in previously untreated patients (PUPs). Jivi is not indicated for the treatment of von Willebrand disease.
Nominal Dosage Strengths[1]	500 IU, 1000 IU, 2000 IU, 3000 IU
Contraindications	History of hypersensitivity reactions to the active substance, polyethylene glycol (PEG), mouse or hamster proteins, or other constituents of the product.
Viral Removal/ Inactivation	20 nm viral filtration
Serum Half-Life (Mean)[3]	See full prescribing information (Table 4)
Stabilizers / Excipients	Glycine, sucrose, histidine, sodium chloride, calcium chloride, polysorbate 80
Rate of Administration	Maximum rate of 2.5 mL/minute. Can usually be infused within 1 to 15 minutes.
Other Administration Considerations[1]	Warm unopened diluent syringe and concentrate vial to a temperature not to exceed 37°C (99°F). Administer as soon as possible after reconstitution. If not administered immediately, store at room temperature for no longer than 3 hours.
Diluent Volume	2.5 mL
Other Package Contents	Sterile Water for Injection, USP in a prefilled diluent syringe, sterile vial adapter, administration set
Storage[4]	Store Jivi at 2°C to 8°C (36°F to 46°F) for up to 24 months from date of manufacture. Within this period, Jivi may be stored for a single period of up to 6 months at temperatures up to 25°C (77°F). Do not freeze.

ESPEROCT®

Intravenous

Product Name	ESPEROCT®
Manufacturer	Novo Nordisk
Manufacturer Contact Number	(877) 668-6777
Product Descriptor	Antihemophilic Factor (Recombinant), Glycopegylated-exei
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	500 IU, 1000 IU, 1500 IU, 2000 IU, 3000 IU, 4000 IU, and 5000 IU
Contraindications	Known hypersensitivity to ESPEROCT or its components, including hamster proteins.
Viral Removal/ Inactivation	Detergent treatment, 20 nm filtration
Serum Half-Life (Mean)	21.7 hours (adults); for children, see full prescribing information
Stabilizers / Excipients	Sodium chloride, L-histidine, sucrose, polysorbate 80, L-methionine, calcium chloride
Rate of Administration	Infuse slowly over approximately 2 minutes.
Other Administration Considerations[1]	Use within 4 hours after reconstitution when stored at ≤86°F (30°C) or within 24 hours when stored in the refrigerator. Inspect for particulate matter and discoloration prior to administration. Do not administer in the same tubing or container with other medicinal products. If necessary, use 0.9% Sodium Chloride Injection, USP to flush the CVAD line before or after ESPEROCT infusion.
Diluent Volume	4 mL
Other Package Contents	MixPro® pre-filled diluent syringe containing 0.9% saline solution, sterile vial adapter with 25-micrometer filter, which serves as a needleless reconstitution device.
Storage[1]	Store in a powder form under refrigeration at 36°F to 46°F (2°C to 8°C) for up to 30 months from the date of manufacture. During the 30-month shelf life, ESPEROCT may be kept at room temperature (RT) up to 86°F (30°C) for no longer than 12 months, or RT up to 104°F (40°C) for no longer than 3 months. Do not freeze. Protect from light.

HEMOFIL® M

Intravenous

Product Name	HEMOFIL® M
Manufacturer	Takeda
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, 1700 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
Stabilizers/Excipients	Albumin, polyethylene glycol, histidine, glycine
Rate of Administration[4]	Infuse at a rate that ensures the comfort of the patient, up to 10 mL per 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	Sterile Water for Injection USP, a double-ended needle and a filter needle
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). Do not freeze.

KOĀTE®

Intravenous

Product Name	KOĀTE®
Manufacturer	Kedrion Biopharma
Manufacturer Contact Number	(855) 353-7466
Product Descriptor	Antihemophilic Factor (Human)
Indications	Control and prevention of bleeding episodes or in order to perform emergency and elective surgery in patients with hemophilia A. Not indicated for the treatment of von Willebrand disease.
Nominal Dosage Strengths[1]	250 IU, 500 IU, 1000 IU
Contraindications	KOĀTE is contraindicated in patients who have had hypersensitivity reactions, including anaphylaxis, to KOĀTE or its components.
Viral Removal/ Inactivation	Solvent/detergent treatment; heated in final container at 80°C for 72 hours
Serum Half-Life (Mean)[3]	16.1 ± 3.2 hours
Stabilizers/Excipients	Albumin (human), polyethylene glycol, polysorbate 80, glycine, histidine
Rate of Administration[4]	The rate of administration should be determined by the patient's comfort level, and no faster than 10 mL per minute.
Other Administration Considerations[4]	Inspect visually for particulate matter and discoloration prior to administration. Bring the vials of KOĀTE and the diluent to room temperature before use. Administer within 3 hours after reconstitution.
Diluent Volume	250 IU/500 IU = 5 mL; 1000 IU = 10 mL
Other Package Contents	SWFI and a Mix2Vial® transfer device
Storage[4]	Store at 2 to 8°C (36 to 46°F). May also be stored at room temperature (up to 25°C ([77°F]) for 6 months. Do not freeze.

Alphanate®

Intravenous

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 adult and pediatric patients with 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]	FVIII: 250 IU, 500 IU, 1000 IU, 1500 IU, 2000 IU (VWF:RCo activity stated on carton and vial label)
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)
Stabilizers/Excipients	Albumin (human); von Willebrand factor also serves as a stabilizing carrier protein for FVIII
Rate of Administration[4]	Do not administer ALPHANATE at a rate exceeding 10 mL/minute
Other Administration Considerations[4]	Ensure that ALPHANATE and diluent are at room temperature (but not above 37 °C) before reconstitution. Inspect for particulate matter and discoloration prior to administration. Use as soon as possible (within 3 hours of reconstitution).
Diluent Volume	250/500 IU = 5 mL; 1000/1500/2000 IU = 10 mL
Other Package Contents	Sterile Water for Injection USP and Mix2Vial® filter transfer set
Storage[4]	Store at a temperatue not to exceed 25°C (77°F). Do not freeze.

Humate-P®

Intravenous

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 von Willebrand disease (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] Humate-P is not indicated for the prophylaxis of spontaneous bleeding episodes in VWD.
Nominal Dosage Strengths[1]	VWF:RCo/FVIII: 600 IU/250 IU; 1200 IU/500 IU; 2400 IU/1000 IU [6]
Contraindications	Anaphylactic or severe systemic reaction to antihemophilic factor or VWF preparations.
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)
Stabilizers/Excipients	-
Rate of Administration[4]	Slowly infuse the solution (maximally 4 mL/minute)
Other Administration Considerations[4]	Inspect for particulate matter and discoloration prior to administration. It is not uncommon for a few flakes or particles to remain after reconstitution; the filter included in the Mix2Vial removes them completely. Ensure that product and diluent are at room temperature prior to reconstitution. Administer within 3 hours after reconstitution.
Diluent Volume	5 mL, 10 mL, 15 mL
Other Package Contents	Sterile Water for Injection USP and Mix2Vial® transfer set
Storage[4]	Store at temperatures up to 25°C (77°F). Do not freeze.

WILATE®

Intravenous

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 (VWD) for: • On-demand treatment and control of bleeding episodes • Perioperative management of bleeding • Routine prophylaxis to reduce the frequency of bleeding episodes (children 6 years of age and older) Adolescents and adults with hemophilia A for: • Routine prophylaxis to reduce the frequency of bleeding episodes • On-demand treatment and control of bleeding episodes
Nominal Dosage Strengths[1]	VWF:RCo/FVIII: 500 IU/500 IU and 1000 IU/1000 IU
Contraindications	Known hypersensitivity reactions, including anaphylactic or severe systemic reactions, 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]
Stabilizers/Excipients	Sucrose, glycine, polysorbate 80, sodium chloride, sodium citrate, calcium chloride
Rate of Administration[4]	2-4 mL/minute
Other Administration Considerations[4]	Warm powder and diluent vials to room temperature before reconsitution. Inspect for particulate matter and discoloration prior to administration. Do not mix with other medicinal products or administer simultaneously with other IV preparation in the same infusion set. Use the solution within 4 hours after reconstitution. 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 two alcohol swabs
Storage[4]	Store 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. 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®

Intravenous

Product Name	VONVENDI®
Manufacturer	Takeda
Manufacturer Contact Number	(800) 828-2088
Product Descriptor	von Willebrand Factor (Recombinant)
Indications	Adults (age 18 and older) with von Willebrand disease for: • On-demand treatment and control of bleeding episodes • Perioperative management of bleeding • Routine prophylaxis to reduce the frequency of bleeding episodes in patients with severe Type 3 von Willebrand disease receiving on-demand therapy.
Nominal Dosage Strengths[1]	650 IU and 1300 IU VWF:RCo
Contraindications	History of life-threatening hypersensitivity reactions to VONVENDI or its components (tri-sodium citrate dihydrate, glycine, mannitol, trehalose-dihydrate, 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]	Slow enough to ensure patient comfort, up to a maximum of 4 mL per 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. Administer immediately after reconstitution; if not, store at room temperature not to exceed 25°C (77°F) for up to 3 hours. Discard any unused reconstituted product after 3 hours.
Diluent Volume	5 mL (650 IU) and 10 mL (1300 IU)
Other Package Contents	Sterile Water for Injection USP and Mix2Vial® reconstitution device
Storage[4]	Store at 2°C to 8°C (36°F to 46°F) or at room temperature not to exceed 30°C (86°F). Do not freeze.

AlphaNine® SD

Intravenous

Product Name	AlphaNine® SD
Manufacturer	Grifols
Manufacturer Contact Number	(800) 520-2807
Product Descriptor	Coagulation Factor IX (Human)
Indications	AlphaNine SD is indicated for the prevention and control of bleeding in patients with Factor IX deficiency due to hemophilia B. 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. This product is also not indicated for the reversal of coumarin anticoagulant-induced hemorrhage, nor in the treatment of hemophilia A patients with inhibitors to Factor VIII.[10]
Dosage Strengths	500 IU, 1000 IU, 1500 IU
Contraindications	None known
Viral Removal/ Inactivation	Solvent/detergent, nanofiltration
Serum Half-Life (Mean)[3]	~21 hours
Stabilizers/Excipients	Dextrose, polysorbate 80, tri(n-butyl) phosphate, heparin
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 the prepared drug as soon as possible within 3 hours after reconstitution.
Diluent Volume	10 mL
Other Package Contents	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). May be stored at room temperature not to exceed 30°C (86°F) for 1 month. Do not freeze to prevent damage to the diluent vial.

BeneFIX®

Intravenous

Product Name	BeneFIX®
Manufacturer	Pfizer
Manufacturer Contact Number	(800) 438-1985
Product Descriptor	Coagulation Factor IX (Recombinant)
Indications	BeneFIX is a recombinant human blood coagulation factor IX indicated for adults and children with hemophilia B (congenital factor IX deficiency or Christmas disease) for: - On-demand treatment and control of bleeding episodes - Perioperative management of bleeding - Routine prophylaxis to reduce the frequency of bleeding episodes BeneFIX is not indicated for induction of immune tolerance in patients with hemophilia B.
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)[3]	23.1 ± 4.4 hours
Stabilizers/Excipients	L-histidine, glycine, sucrose, polysorbate 80 and sodium chloride.
Rate of Administration[4]	Administer over a period of several minutes. Adjust the rate of administration based on the patient's comfort level.
Other Administration Considerations[4]	Inspect for particulate matter and discoloration prior to administration. Reconstituted product should appear clear and colorless. Blood should not enter the syringe. Store reconstituted solution at room temperature and use it 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 syringe with 0.234% sodium chloride diluent, vial adapter reconstitution device, sterile infusion set, two alcohol swabs, one bandage and one gauze pad.
Storage[4]	Store BeneFIX at room temperature or under refrigeration at a temperature of 2°C to 30°C (36°F to 86°F). Do not freeze to prevent damage to the diluent syringe.

IXINITY®[8]

Intravenous

Product Name	IXINITY®
Manufacturer	Medexus Pharma
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: • On-demand treatment and control of bleeding episodes • Perioperative management • Routine prophylaxis to reduce the frequency of bleeding episodes IXINITY is not indicated for induction of immune tolerance in patients with hemophilia B.
Dosage Strengths	250 IU, 500 IU, 1000 IU, 1500 IU, 2000 IU, 3000 IU
Contraindications	Patients with known hypersensitivity to IXINITY or its excipients, including hamster protein.
Viral Removal/ Inactivation	Solvent/detergent treatment, chromatographic step, nanofiltration
Serum Half-Life (Mean)	24 ± 7 hours
Stabilizers/Excipients	Histidine, mannitol, trehalose dihydrate, 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. Infuse reconstituted solution immediately or within 3 hours of storage at room temperature after reconstitution.
Diluent Volume	5 mL
Other Package Contents	10 mL syringe pre-filled with 5 mL of Sterile Water for Injection USP with plunger rod attached, vial adapter with filter.
Storage[4]	250 IU strength only: store at 2°C to 8°C (36°F to 46°F). All other strengths: store at 2°C to 25°C (36°F to 77°F). Do not freeze.

RIXUBIS®

Intravenous

Product Name	RIXUBIS®
Manufacturer	Takeda
Manufacturer Contact Number	(800) 828-2088
Product Descriptor	Coagulation Factor IX (Recombinant)
Indications	In adults and children with hemophilia B for: • On-demand treatment and control of bleeding episodes • Perioperative management of bleeding • Routine prophylaxis to reduce the frequency of bleeding episodes Not indicated for induction of immune tolerance in patients with hemophilia B.
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 for particulate matter and discoloration prior to administration. Allow RIXUBIS and Sterile Water for Injection USP to reach room temperature before reconstitution. Administer at room temperature and within 3 hours of reconstitution. Do not refrigerate after reconstitution.
Diluent Volume	5 mL
Other Package Contents	Sterile Water for Injection USP and a BAXJECT II transfer device.
Storage[4]	Store at refrigerated temperature [2°C to 8°C (36°F to 46°F)] or room temperature [not to exceed 30°C (86°F)]. Do not freeze.

ALPROLIX®

Intravenous

Product Name	ALPROLIX®
Manufacturer	Sanofi
Manufacturer Contact Number	(800) 633-1610
Product Descriptor	Coagulation Factor IX (Recombinant), Fc Fusion Protein
Indications	In adults and children with hemophilia B: • On-demand treatment and control of bleeding episodes • Perioperative management of bleeding • Routine prophylaxis to reduce the frequency of bleeding episodes Not indicated for induction of immune tolerance in patients with hemophilia B.
Dosage Strengths	250 IU, 500 IU, 1000 IU, 2000 IU, 3000 IU, 4000 IU
Contraindications	Known history of hypersensitivity reactions, including anaphylaxis, to the product or its excipients.
Viral Removal/Inactivation	Detergent treatment, 15 nm filtration
Serum Half-Life (Mean)[3]	Varies by age range; see Prescribing Information.
Stabilizers/Excipients	Mannitol, L-histidine, Mannitol, L-histidine, sucrose, sodium chloride, 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]	Allow ALPROLIX and diluent to reach room temperature before use. Administer the product as soon as possible, but no later than 3 hours after reconstitution. Do not refrigerate after reconstitution.
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 one sterile vial adapter (reconstitution device).
Storage[4]	Store at 2°C to 8°C (36°F to 46°F). Can be stored at room temperature, not to exceed 30°C (86°F), for a single period up to 6 months within the expiration date. Use the product before the end of this 6-month period or discard it. Do not place product back into refrigeration after warming to room temperature. Do not freeze to prevent damage to prefilled diluent syringe.

IDELVION®

Intravenous

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 treatment and control of bleeding episodes • Perioperative management of bleeding • Routine prophylaxis to reduce the frequency of bleeding episodes • Not indicated for induction of immune tolerance in patients with hemophilia B
Dosage Strengths	250 IU, 500 IU, 1000 IU, 2000 IU, 3500 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)[3]	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. Ensure the vials of IDELVION and the Sterile Water for Injection USP are at room temperature before mixing. Use immediately or within 4 hours of reconstitution. Store reconstituted solution at room temperature. Do not refrigerate after reconstitution.
Diluent Volume	250/500/1000 IU = 2.5 mL; 2000/3500 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.

REBINYN®

Intravenous

Product Name	REBINYN®
Manufacturer	Novo Nordisk
Manufacturer Contact Number	(877) 668-6777
Product Descriptor	Coagulation Factor IX (Recombinant), GlycoPEGylated
Indications	In adults and children with hemophilia B for: • On-demand treatment and control of bleeding episodes • Perioperative management of bleeding • Routine prophylaxis to reduce the frequency of bleeding episodes Not indicated for immune tolerance induction in patients with hemophilia B.
Nominal Dosage Strengths[1]	500 IU, 1000 IU, 2000 IU, 3000 IU
Contraindications	Known hypersensitivity reactions to REBINYN or its components, including hamster proteins
Viral Removal/Inactivation	Detergent treatment, 20 nm viral filtration
Serum Half-Life (Mean)[3]	Varies by patient age; see full prescribing information
Stabilizers/Excipients	Sodium chloride, histidine, sucrose, mannitol, polysorbate 80
Rate of Administration	Infuse slowly over 1 to 4 minutes
Other Administration Considerations	Bring the REBINYN vial and pre-filled diluent syringe to room temperature. Use within 4 hours after reconstitution when stored at room temperature ≤ 86°F (30°C).
Diluent Volume	4 mL
Other Package Contents	Histidine solution in a MixPro® prefilled diluent syringe, sterile vial adapter with 25 micrometer filter which serves as a needleless reconstitution device.
Storage[4]	Store REBINYN under refrigeration at 36°F to 46°F (2°C to 8°C) for up to 24 months from date of manufacture. Within this period, may be stored at room temperature not to exceed 86°F (30°C) for up to 6 months. Do not freeze.

FEIBA®

Intravenous

Product Name	FEIBA®
Manufacturer	Takeda
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 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[11]
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 myocardial infarction)
Viral Removal/ Inactivation	35 nm nanofiltration and vapor heat treatment
Serum Half-Life (Mean)[3]	-
Stabilizers/Excipients	Trisodium citrate, sodium chloride
Rate of Administration[4]	Must not exceed 10 units per kg of body weight per minute.
Other Administration Considerations[4]	Inspect visually for particulate matter and discoloration prior to administration. Prior to reconstitution, allow the vials of FIEBA and diluent to reach room temperature. 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	500 units = 10 mL; 1000 units = 20 mL; 2500 units = 50 mL
Other Package Contents	Sterile Water for Injection USP, and a BAXJECT II Hi-Flow Needleless Transfer Device
Storage[4]	Store at 36°F to 77°F (2°C to 25°C). Do not freeze.

NovoSeven® RT

Intravenous

Product Name	NovoSeven® RT
Manufacturer	Novo Nordisk
Manufacturer Contact Number	(877) 668-6777
Product Descriptor	Coagulation Factor VIIa (Recombinant)
Indications	• Treatment of bleeding episodes and perioperative management in adults and children with hemophilia A or B with inhibitors, congenital Factor VII (FVII) deficiency, and Glanzmann's thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets • Treatment of bleeding episodes and perioperative management in adults with acquired hemophilia
Dosage Strengths	1 mg (1000 mcg), 2 mg (2000 mcg), 5 mg (5000 mcg) and 8 mg (8000 mcg)
Contraindications	None known.
Viral Removal/ Inactivation	NovoSeven RT purification process
Serum Half-Life (Mean)	Half-life varies by patient age and inhibitor status; refer to full prescribing information.
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]	Administer within 3 hours after reconstitution; discard any unused product. Inspect visually for particulate matter and discoloration prior to administration. Do not mix with other 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 syringe with 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.

SEVENFACT®

Intravenous

Product Name	SEVENFACT®
Manufacturer	HEMA Biologics
Manufacturer Contact Number	(855) 718-4362
Product Descriptor	Coagulation factor VIIa (recombinant)-jncw
Indications	Treatment and control of bleeding episodes occurring in adults and adolescents (12 years of age and older) with hemophilia A or B with inhibitors. SEVENFACT is not indicated for treatment of congential factor VII deficiency.
Nominal Dosage Strengths[1]	1 mg (1000 mcg), 5 mg (5000 mcg)
Contraindications	Known allergy to rabbits or rabbit proteins. Severe hypersensitivity reaction to SEVENFACT or any of its components.
Viral Removal/ Inactivation	Unspecified purification steps validated to inactivate or remove a panel of model viruses
Serum Half-Life (Mean)[3]	1.4 hours (225 mcg/kg dose); 1.7 hours (75 mcg/kg dose)
Stabilizers/Excipients	Arginine, glycine, isoleucine, lysine, polysorbate 80, trisodium citrate dihydrate.
Rate of Administration[4]	Infuse over 2 minutes or less as a bolus IV infusion
Other Administration Considerations[4]	Bring lyophilized powder and pre-filled syringe to room temperature. Visually inspect reconstituted solution for particulate matter and discoloration. The reconstituted solution should be stored in the vial at room temperature, but can be stored between 36°F to 86°F (2°C to 30°C) for up to 4 hours after reconstitution. SEVENFACT must be infused within 4 hours after reconstitution.
Diluent Volume	1.1 mL (1 mg), 5.2 mL (5 mg)
Other Package Contents	Pre-filled syringe containing Sterile Water for Injection; vial adapter with 5 micron filter
Storage[4]	SEVENFACT kit should be stored at room temperature but can be stored between 36°F to 86°F (2°C to 30°C). Do not freeze.

OBIZUR®[8]

Intravenous

Product Name	OBIZUR®
Manufacturer	Takeda
Manufacturer Contact Number	(800) 828-2088
Product Descriptor	Antihemophilic Factor (Recombinant), Porcine Sequence
Indications	• On-demand treatment and control of bleeding episodes in adults with acquired hemophilia A. • 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. • OBIZUR is not indicated for the treatment of von Willebrand disease.
Dosage Strengths	500 units
Contraindications	Do not use in (1) patients who have had life-threatening hypersensitivity reactions to OBIZUR or its component (including traces of hamster proteins), or (2) patients with congential hemophilia A with inhibitors.
Viral Removal/ Inactivation	Solvent/detergent, nanofiltration
Serum Half-Life (Mean)[3]	-
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 medicinal 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 adapter with filter
Storage[4]	Store OBIZUR at refrigeration temperature of 2°C to 8°C (36°F to 46°F). Do not freeze.

HEMLIBRA®

Subcutaneous

Product Name	HEMLIBRA®
Manufacturer	Genentech
Manufacturer Contact Number	(888) 821-8590
Product Descriptor	Emicizumab-kxwh
Indications	Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients ages newborn and older with hemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors.
Nominal Dosage Strengths[1]	12 mg/0.4 mL; 30 mg/mL; 60 mg/0.4 mL; 105 mg/0.7 mL; 150 mg/mL; 300 mg/2 mL (150 mg/mL)
Contraindications	None
Viral Removal/ Inactivation	-
Serum Half-Life (Mean)	Absorption: 1.6 ± 1 day; Elimination: 26.9 ± 9.1 days
Stabilizers/Excipients	L-arginine, L-histidine, poloxamer 188, and L-aspartic acid.
Rate of Administration[4]	Subcutaneous delivery; see full prescribing information.
Other Administration Considerations[4]	Visually inspect HEMLIBRA for particulate matter and discoloration before administration. See full prescribing information for other administration instructions.
Diluent Volume	None (liquid form)
Other Package Contents	None
Storage[4]	Store HEMLIBRA vials in a refrigerator at 2°C to 8°C (36°F to 46°F). If needed, unopened vials of HEMLIBRA can be stored out of and then returned to the refrigerator. The temperature and total combined time out of refrigeration should not exceed 30°C (86°F) and 7 days (at a temperature below 30°C [86°F]), respectively. Do not freeze. Do not shake.

Profilnine®

Intravenous

Product Name	Profilnine®
Manufacturer	Grifols
Manufacturer Contact Number	(800) 520-2807
Product Descriptor	Factor IX Complex
Indications	Profilnine, Factor IX Complex, is indicated for the prevention and control of bleeding in patients with factor IX deficiency (hemophilia B). Profilnine contains non-therapeutic levels of factor VII and is not indicated for use in the treatment of factor VII deficiency.
Dosage Strengths	500 IU, 1000 IU, 1500 IU
Contraindications	None known
Viral Removal/ Inactivation	Solvent/detergent treatment, nanofiltration
Serum Half-Life (Mean)[3]	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 hours 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]	Store at a temperature not to exceed 25°C (77°F). Do not freeze.

BALFAXAR®

Intravenous

Product Name	BALFAXAR®
Manufacturer	Octapharma USA
Manufacturer Contact Number	(888) 429-4535
Product Descriptor	Prothrombin Complex Concentrate, Human-lans
Indications	Urgent reversal of acquired coagulation factor deficiency induced by Vitamin K antagonist (VKA, e.g., warfarin) therapy in adult patients with need for an urgent surgery/invasive procedure.
Dosage Strengths	(Factor IX). See full prescribing information for potency ranges for Factors II, VII and X, Protein C and Protein S.
Contraindications	• Known anaphylactic or severe systemic reactions to BALFAXAR or any of the components of the product. • Known allergy to heparin or history of heparin-induced thrombocytopenia (HIT). • IgA deficient patients with known antibodies against IgA.
Viral Removal/ Inactivation	Solvent/detergent (S/D) and nanofiltration
Serum Half-Life (Mean)[3]	Not specified
Stabilizers/Excipients	Heparin and sodium citrate
Rate of Administration[4]	0.12 ml/kg/min (approximately 3 units/kg/min) up to a maximum rate of 8.4 mL/min (approximately 210 units/min)
Other Administration Considerations[4]	Reconstituted products should be inspected visually for particulate matter. Do not use solutions that are cloudy or have deposits. If the lyophilized powder fails to dissolve completely or an aggregate is formed, do not use the preparation. After reconstitution, administration should begin promptly or within 8 hours, provided sterility is maintained. If the same patient is to receive more than one vial, you may pool the contents of multiple vials, provided sterility is maintained. Use a separate unused transfer device for the reconstitution of each product vial.
Diluent Volume	500 Factor IX units in 20 ml reconstitution volume; 1000 Factor IX units in 40 ml reconstitution volume
Other Package Contents	Sterile Water for Injection, transfer device (Nextaro®) for reconstitution.
Storage[4]	Store for up to 36 months at 2°C to 25°C (36°F to 77°F) from the date of manufacture. Do not freeze.

Kcentra®

Intravenous

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 (Factor IX). See full prescribing information for potency ranges for Factors II, VII and X, Protein C and Protein S.
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	Heat treatment at 60°C for 10 hours, nanofiltration
Serum Half-Life (Mean)	See full prescribing information. (Section 12.3 Pharmacokinetics [Table 9])
Stabilizers/Excipients	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. Reconstituted product can be stored at 2°C to 25°C (36°F to 77°F). If cooled, the solution should be warmed to 20°C to 25°C (68°F to 77°F) prior to administration. Do not freeze the reconstituted product. After reconstitution, administration should 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.

COAGADEX®[8]

Intravenous

Product Name	COAGADEX®
Manufacturer	Kedrion Biopharma
Manufacturer Contact Number	(866) 353-7466
Product Descriptor	Coagulation Factor X (Human)
Indications	Adults and children with hereditary Factor X deficiency for: • Routine prophylaxis to reduce the frequency of bleeding episodes • On-demand treatment and control of bleeding episodes • Perioperative management of bleeding in patients with mild, moderate, and severe 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.
Viral Removal/ Inactivation	Solvent/detergent, 15-nm filtration, terminal dry heat
Serum Half-Life (Mean)[3]	30.3 hours
Stabilizers/Excipients	Chloride, phosphate, citrate, sucrose, sodium
Rate of Administration[4]	Suggested rate of 10 mL/min, but 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 or within one hour of reconstitution.
Diluent Volume	250 IU = 2.5 mL; 500 IU = 5 mL
Other Package Contents	Sterile Water for Injection USP and Mix2Vial® transfer device
Storage[4]	Store in a refrigerator or at room temperature (36°F to 86°F). Do not freeze.

ANDEXXA®

Intravenous

Product Name	ANDEXXA®
Manufacturer	AstraZeneca
Manufacturer Contact Number	(800) 236-9933
Product Descriptor	Coagulation Factor Xa (Recombinant), Inactivated-zhzo
Indications	Patients treated with rivaroxaban and apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding. This indication is approved under accelerated approval based on the change from baseline in anti-FXa activity in healthy volunteers. An improvement in hemostasis has not been established. Continued approval for this indication may be contingent upon the results of studies to demonstrate an improvement in hemostasis in patients. ANDEXXA has not been shown to be effective for, and is not indicated for, the treatment of bleeding related to any FXa inhibitors other than apixaban and rivaroxaban.
Nominal Dosage Strengths[1]	200 mg 4-ctn, 200 mg 5-ctn
Contraindications	None
Viral Removal/ Inactivation	Nanofiltration, detergent
Serum Half-Life (Mean)[3]	Low dose (400 mg): 3.3 hours (range 2.3 - 4.0 hours) High dose (800 mg): 2.7 hours (range 1.9 – 3.4 hours)
Stabilizers/Excipients	Tromethamine (Tris base), Tris hydrochloride, L-arginine hydrochloride, sucrose, mannitol, polysorbate 80
Rate of Administration[4]	Initial IV bolus with a target rate of 30 mg/min, followed within 2 minutes by continuous IV infusion (4 mg/min for 400 mg dose, 8 mg/min for 800 mg dose) for up to 120 minutes
Other Administration Considerations[4]	Administer using a 0.2 or 0.22 micron in-line polyethersulfone or equivalent low protein-binding filter. Reconstituted ANDEXXA in vials is stable at room temperature for up to 8 hours, or may be stored for up to 24 hours at 2°C to 8°C. Reconstituted ANDEXXA in IV bags is stable at room temperature for up to 8 hours.
Diluent Volume	20 mL Sterile Water for Injection USP (not supplied)
Other Package Contents	None
Storage[4]	Store refrigerated at 2°C to 8°C (36°F to 46°F). Do not freeze.

Corifact®

Intravenous

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 (Actual Factor XIII potency stated on vial label and carton)
Contraindications	Patients with known anaphylactic or severe systemic reactions to human plasma-derived products.
Viral Removal/ Inactivation	Heat-treatment, 20 nm filtration, precipitation/adsorption, ion exchange chromatography
Serum Half-Life (Mean)[3]	7.1 ± 2.74 days (adults); 5.7 ± 1.00 days (age <16 years)
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
Storage[4]	Refrigerate at 2°C to 8°C (36°F to 46°F). May be stored at room temperature not to exceed 25°C (77°F) for up to 6 months. Do not return the product to the refrigerator after it is stored at room temperature. Do not freeze.

TRETTEN®[8]

Intravenous

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 congenital factor XIII A-subunit deficiency. Not for use in patients with congenital factor XIII B-subunit deficiency.
Dosage Strengths	2000-3125 IU (the actual amount in IU is stated on each carton and vial)
Contraindications	Hypersensitivity to the active substance or to any of the excipients.
Viral Removal/ Inactivation	–
Serum Half-Life (Mean)[3]	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 and discoloration; do not administer if either is observed. Do not administer with other infusion solutions. Do not administer as drip. Use reconstituted TRETTEN immediately. If not used immediately, store refrigerated or at room temperature not to exceed 25°C (77°F) for up to 3 hours. Discard after 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.

RiaSTAP®

Intravenous

Product Name	RiaSTAP®
Manufacturer	CSL Behring
Manufacturer Contact Number	(800) 504-5434
Product Descriptor	Fibrinogen Concentrate (Human)
Indications	Treatment of acute bleeding episodes in adult and pediatric patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia. Not indicated for dysfibrinogenemia.
Dosage Strengths	900-1300 mg (actual potency is printed on the vial label and carton)
Contraindications	Known anaphylactic or severe systemic reactions to human plasma-derived products.
Viral Removal/ Inactivation	Cryoprecipitation, heat treatment, glycine precipitation steps, lyophilization
Serum Half-Life (Mean)[3]	78.7 ± 18.13 hours
Stabilizers/Excipients	Human albumin, L-arginine hydrochloride, sodium chloride, sodium citrate
Rate of Administration[4]	Slow IV injection at a rate not exceeding 5 mL per minute.
Other Administration Considerations[4]	Inspect for particulate matter and discoloration; do not administer if the solution is cloudy or contains particulates. Discard partially used vials. Reconstitute at room temperature and administer at room temperature. RiaSTAP is stable for 8 hours after reconstitution when stored at 20-25°C; administer within this time period.
Diluent Volume	50 mL
Other Package Contents	-
Storage[4]	When stored at temperatures of 2-8°C (36-46°F), RIASTAP is stable for the period indicated by the expiration date on the carton and vial label (up to 60 months). Do not freeze.

FIBRYGA®

Intravenous

Product Name	FIBRYGA®
Manufacturer	Octapharma USA
Manufacturer Contact Number	(888) 429-4535
Product Descriptor	Fibrinogen (Human)
Indications	Fibrinogen supplementation in bleeding patients with acquired fibrinogen deficiency. Treatment of acute bleeding episodes in adults and adolescents with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia. FIBRYGA is not indicated for dysfibrinogenemia.
Dosage Strengths	1g
Contraindications	Individuals who have manifested severe immediate hypersensitivity reactions, including anaphylaxis, to FIBRYGA or its components.
Viral Removal/ Inactivation	Solvent/detergent treatment, nanofiltration
Serum Half-Life (Mean)[3]	75.9 ± 23.8 hours
Stabilizers/Excipients	Glycine, L-arginine hydrochloride, sodium citrate dihydrate, sodium chloride
Rate of Administration[4]	Should be determined by the patient's comfort level. Maximum rates of 20 mL/minute in acquired fibrinogen deficiency, and 5 mL/minute in congenital fibrinogen deficiency.
Other Administration Considerations[4]	Inspect reconstituted FIBRYGA solution in the syringe for visible particulate matter and discoloration prior to administration; should be almost colorless and slightly opalescent. After reconstitution, do not refrigerate or freeze. Use the reconstituted FIBRYGA solution immediately or within 4 hours after reconstitution. Discard any remaining FIBRYGA solution.
Diluent Volume	50 mL Sterile Water for Injection USP (not provided)
Other Package Contents	Transfer device (Octajet), 17-micron particle filter
Storage[4]	Store at 2°C to 25°C (36°F to 77°F). Do not freeze.

RYPLAZIM®

Intravenous

Product Name	RYPLAZIM®
Manufacturer	Kedrion Biopharma
Manufacturer Contact Number	(866) 353-7466
Product Descriptor	Plasminogen, Human-tvmh
Indications	Treatment of patients with plasminogen deficiency type 1 (hypoplasminogenemia)
Nominal Dosage Strengths[1]	68.8 mg
Contraindications	Known hypersensitivity to plasminogen or other components of RYPLAZIM®
Viral Removal/ Inactivation	Affinity chromatography, solvent/detergent treatment, 20 nm nanofiltration
Serum Half-Life (Mean)[3]	39.2 ± 6.2 hours
Stabilizers/Excipients	Sodium citrate, sodium chloride, glycine, sucrose
Rate of Administration[4]	Infuse the total dose slowly over 10-30 minutes (approximately 5 mL/ minute). Using a timer (e.g. watch or clock), push the plunger of the syringe approximately 1 mL every 12 seconds.
Other Administration Considerations[4]	Allow RYPLAZIM vials to equilibrate to room temperature before reconstitution. Do not refrigerate after reconstitution. Administer within 3 hours following reconstitution. Administer by a separate infusion. Do not administer RYPLAZIM with other medications.
Diluent Volume	12.5 mL of Sterile Water for Injection (SWFI) per vial (not supplied)
Other Package Contents	-
Storage[4]	Store between 2°C to 8°C (36°F to 46°F). Do not freeze.

KEY AND FOOTNOTES

KEY

IU: international unit
FVIII: factor VIII
RCo: Ristocetin cofactor
VWD: von Willebrand disease
VWF: von Willebrand factor

FOOTNOTES

1. See full prescribing information for actual dosage ranges corresponding to each nominal product strength.
2. Nominal strengths; see full prescribing information for factor VIII potency ranges for each strength.
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 and by age; 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. Actual number of units of factor VIII inhibitor bypassing activity is stated on the label of each vial.

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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