

Product Specifics	AFSTYLA® CSL Behring	ELOCTATE™ Biogen	ADYNOVATE Shire
<b>Indications</b>	<p>AFSTYLA®, Antihemophilic Factor (Recombinant), Single Chain, is a recombinant, antihemophilic factor indicated in adults and children with hemophilia A (congenital Factor VIII deficiency) for:</p> <ul style="list-style-type: none"> <li>On-demand treatment and control of bleeding episodes,</li> <li>Routine prophylaxis to reduce the frequency of bleeding episodes,</li> <li>Perioperative management of bleeding.</li> </ul>	<p>ELOCTATE [Antihemophilic Factor (Recombinant), Fc Fusion Protein] is a recombinant DNA derived, antihemophilic factor indicated in adults and children with Hemophilia A (congenital Factor VIII deficiency) for:</p> <ul style="list-style-type: none"> <li>On-demand treatment and control of bleeding episodes</li> <li>Perioperative management of bleeding</li> <li>Routine prophylaxis to reduce the frequency of bleeding episodes.</li> </ul> <p>ELOCTATE is not indicated for the treatment of von Willebrand disease.</p>	<p>ADYNOVATE, Antihemophilic Factor (Recombinant), PEGylated, is a human antihemophilic factor indicated in adolescent and adult patients (12 years and older) with hemophilia A (congenital factor VIII deficiency) for:</p> <ul style="list-style-type: none"> <li>On-demand treatment and control of bleeding episodes</li> <li>Routine prophylaxis to reduce the frequency of bleeding episodes</li> </ul> <p>ADYNOVATE is not indicated for the treatment of von Willebrand disease</p>
<b>Contraindications</b>	Do not use in patients who have had life-threatening hypersensitivity reactions, including anaphylaxis to AFSTYLA or its excipients, or hamster proteins.	ELOCTATE is contraindicated in patients who have had life-threatening hypersensitivity reactions to ELOCTATE, including anaphylaxis.	ADYNOVATE is contraindicated in patients who have had prior anaphylactic reaction to ADYNOVATE, to the parent molecule (ADVATE), mouse or hamster protein, or excipients of ADYNOVATE (e.g. Tris, mannitol, trehalose, glutathione, and/or polysorbate 80).
<b>Nutrient in Cell Culture</b>	No human or animal derived proteins are used in the purification or formulation processes.	BDD-rFVIIIc is produced by recombinant DNA technology from a human embryonic kidney (HEK) cell line, which has been extensively characterized. The HEK cell line expresses BDD-rFVIIIc into a defined, cell culture medium that does not contain any proteins derived from animal or human sources.	The cell culture, pegylation, purification process and formulation used in the manufacture of ADYNOVATE do not use additives of human or animal origins.
<b>Stabilizer in Final Formulation</b>	The reconstituted product contains the excipients: L-Histidine, polysorbate 80, calcium chloride, sodium chloride, sucrose, water.	The reconstituted product contains the excipients: sucrose, sodium chloride, L-histidine, calcium chloride and polysorbate 20.	Tris (hydroxymethyl) aminomethane, Calcium Chloride, Mannitol, Sodium Chloride, Trehalose Dihydrate, Glutathione, Histidine, Polysorbate. There are no additives of human or animal origin.
<b>Viral Safety Processes</b>	AFSTYLA is purified by a controlled multi-step process including two virus reduction steps complementing each other in their mode of action.	BDD-rFVIIIc is purified using a series of chromatography steps, including affinity capture with a recombinant, single chain antibody fragment produced in a yeast expression system. No human or animal derived proteins are used in the purification or formulation processes. The production process also incorporates two dedicated viral clearance steps - a detergent treatment step for inactivation and a 15 nm filtration step for removal of viruses.	ADVATE is purified from the culture medium using a series of chromatography columns. The purification process includes an immunoaffinity chromatography step in which a monoclonal antibody directed against factor VIII is employed to selectively isolate the factor VIII from the medium. The production process includes a dedicated, viral inactivation solvent-detergent treatment step. The ADVATE molecule is then covalently conjugated with the polyethylene glycol, which mainly targets lysine residues.
<b>Product Half Life</b>	0 to <6 years; 10.4 ≥6 to <12 years; 10.2 12 to <18 years; 14.3 ≥18 years; 14.2	Adults: 19.7 + 2.3 hours 12-17 years: 16.4 + 2.3 hours 6-11 years: 14.6 + 3.1 hours 2-5 years: 12 + 2.45 hours	12 to <18 years; 13.43 ± 4.05 ≥18 years; 14.69 ± 3.79
<b>Product Recovery Percentage</b>	0 to <6 years; 1.6 ≥6 to <12 years; 1.66 12 to <18 years; 1.69 ≥18 years; 2.00	Adults: 2.26 + .14 IU/dL per IU/kg 12-17 years: 1.85 + .27 IU/dL per IU/kg 6-11 years: 2.44 + .42 IU/dL per IU/kg 2-5 years: 1.89 + .14 IU/dL per IU/kg	12 to <18 years; 2.12 ± 0.60 ≥18 years; 2.66 ± 0.68
<b>Storage Requirements</b>	<ul style="list-style-type: none"> <li>Store AFSTYLA in the original package to protect the AFSTYLA vials from light.</li> <li>Store AFSTYLA in powder form at 2°C to 8°C (36°F to 46°F). Do not freeze to avoid damage to the diluent vial. AFSTYLA 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 printed on the carton and vial labels.</li> <li>Record the starting date of room temperature on the unopened product carton. 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.</li> <li>Do not use AFSTYLA after the expiration date indicated on the vial.</li> <li>The reconstituted product (after mixing dry product with diluent) can be stored at 2°C to 8°C (36°F to 46°F), or at room temperature, not to exceed 25°C (77°F), for up to 4 hours.</li> <li>Protect from direct sunlight.</li> <li>After reconstitution, if the product is not used within 4 hours, it must be discarded.</li> <li>Do not use AFSTYLA if the reconstituted solution is cloudy or has particulate matter.</li> <li>Discard any unused AFSTYLA.</li> </ul>	<p>Prior to reconstitution:</p> <ul style="list-style-type: none"> <li>Store ELOCTATE in the original package to protect the ELOCTATE vials from light.</li> <li>Store ELOCTATE in powder form at 2°C to 8°C (36°F to 46°F). Do not freeze to avoid damage to the pre-filled diluent syringe.</li> <li>ELOCTATE may be stored at room temperature, not to exceed 30°C (86°F), for a single period of up to 6 months, within the expiration date printed on the label.</li> <li>If stored at room temperature, record the date that ELOCTATE is removed from refrigeration on the carton in the area provided. After storage at room temperature, do not return the product to the refrigerator.</li> <li>Do not use beyond the expiration date printed on the vial or 6 months after the date that was written on the carton, whichever is earlier.</li> </ul> <p>After Reconstitution:</p> <ul style="list-style-type: none"> <li>The reconstituted product may be stored at room temperature, not to exceed 30°C (86°F), for up to 3 hours. Protect from direct sunlight. After reconstitution, if the product is not used within 3 hours, it must be discarded.</li> <li>Do not use ELOCTATE if the reconstituted solution is cloudy or has particulate matter.</li> <li>Discard any unused ELOCTATE.</li> </ul>	<ul style="list-style-type: none"> <li>Store ADYNOVATE in powder form at 2° to 8°C (36° to 46°F). Do not freeze.</li> <li>ADYNOVATE may be stored at room temperature not to exceed 30°C (86°F) for a period of up to 1 month not to exceed the expiration date. If stored at room temperature, write the date on the carton when ADYNOVATE is removed from refrigeration.</li> <li>After storage at room temperature, do not return the product to the refrigerator.</li> <li>Do not use beyond expiration date printed on the carton or housing.</li> <li>Store ADYNOVATE in the original box and protect from extreme exposure to light. Administer ADYNOVATE as soon as possible, but no later than 3 hours after reconstitution.</li> <li>Do not refrigerate after reconstitution</li> </ul>
<b>Shelf Life from Date of Manufacture</b>	36 months	36 months from date of manufacture	24 months
<b>How Supplied / Diluent Volume</b>	250, 500, 1000 IU in 2.5mL or 2000 IU, 3000 IU in 5mL	250 IU - 3mL, 500 IU - 3mL, 750 IU - 3mL, 1000 IU - 3mL, 1500 IU - 3mL, 2000 IU - 3mL, 3000 IU - 3mL	5 mL