On-demand treatment and control of bleeding episodes, Do not use AFSTYLA after the expiration date indicated on the vial. 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. After storage at room temperature, do not return the product to the refrigerator. Perioperative management of bleeding.

Routine prophylaxis to reduce the frequency of bleeding episodes. Do not use AFSTYLA if the reconstituted solution is cloudy or has particulate matter. After reconstitution, if the 12-17 years; 1.85 ± 0.27 IU/dL per IU/kg
12-17 years; 16.4 ± 2.3 hours
6-11 years; 14.6 ± 3.1 hours
2-5 years; 12 ± 2.45 hours

0 to <6 years; 10.4
26 to <12 years; 10.2
12 to <18 years; 14.2
≥18 years; 14.2

Adults: 2.26 ± 1.4 IU/L, per µg/kg
12-17 years; 1.86 ± 0.27 IU/L, per µg/kg
6-11 years; 2.44 ± 4.2 IU/L, per µg/kg
2-5 years; 1.89 ± 1.4 IU/L, per µg/kg

12 to <18 years; 1.34 ± 0.45 µg/kg
≥18 years; 14.69 ± 3.79 µg/kg

Storage Requirements

• Store AFSTYLA in the original package to protect the AFSTYLA vials from light.
• 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.
• 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.
• Do not use AFSTYLA after the expiration date indicated on the vial.
• 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. Protect from direct sunlight.
• After reconstitution, if the product is not used within 4 hours, it must be discarded.
• Do not use AFSTYLA if the reconstituted solution is cloudy or has particulate matter. Discard any unused AFSTYLA.

Shelf Life from Date of Manufacture

36 months

How Supplied / Diluent Volume

250, 500, 1000 IU in 2.5mL or 2000 IU in 5mL.
250 IU - 3mL, 500 IU - 3mL, 750 IU - 3mL, 1000 IU - 3mL, 1500 IU - 3mL, 2000 IU - 3mL, 3000 IU - 3mL

Disclaimers: Information provided herein is a summary of available information only. This summary has been compiled by BD Pharma and does not represent a clinical comparison conducted by any manufacturer referenced from specific product brands, etc. It should be used as a reference only. For a copy of a package insert or to request any additional information, please contact us at 1-800-948-9834.