Afstyla

(antihemophilic factor [recombinant] single chain)

New Product Slideshow

MPR

Introduction

- **Brand name:** Afstyla
- **Generic name:** Antihemophilic Factor (recombinant), single chain
- **Pharmacological class:** Clotting factor
- **Strength and Formulation:** 250 IU, 500 IU, 1000 IU, 2000 IU, 3000 IU; lyophilized pwd for IV infusion after reconstitution; preservative-free
- **Manufacturer:** CSL Behring
- **How supplied:** Kit—1 (vial w. diluent and supplies)
- **Legal Classification:** Rx

AFSTYLA


NDC 69911-474-02
250 IU Range
AFSTYLA®
Antihemophilic Factor (Recombinant), Single Chain
One single-use vial containing lyophilized powder for reconstitution.
For Intravenous Administration Only
℞ only
(01)10369911474025
CSL Behring
NDC 69911-484-01
AFSTYLA®
Antihemophilic Factor
For Intravenous Administration
℞ only
CSL

Indications

- **In patients with Hemophilia A**: to treat and control bleeding episodes, for perioperative management, and routine prophylaxis to reduce the frequency of bleeding episodes

Limitations of use

- **Not** for treating von Willebrand disease

Dosage & Administration

- Dosage Required (IU) = Body Weight (kg) × Desired % Factor VIII Increase × 0.5
- Individualize
- Max infusion rate: 10mL/min
- **Bleeding**:
  - **Minor**: obtain 20–40% FVIII increase; may repeat every 12–24hrs until resolved
  - **Moderate**: obtain 30–60% FVIII increase; may repeat every 12–24hrs until resolved
  - **Major**: obtain 60–100% FVIII increase; may repeat every 8–24hrs until resolved

Dosage & Administration

- **Perioperative**:
  - **Minor**: obtain 30–60% FVIII increase; may repeat every 24hrs for ≥1 day until healed
  - **Major**: obtain 80–100% FVIII increase; may repeat every 8–24hrs until adequately healed, then continue for ≥7 days to maintain Factor VIII activity of 30–60%
- **Routine prophylaxis**:
  - **≥12yrs**: 20–50 IU/kg 2–3 times weekly
  - **<12yrs**: 30–50 IU/kg 2–3 times weekly (more frequent or higher doses may be required)

Considerations for Special Populations

- **Pregnancy:** Give only if clearly needed
- **Nursing mothers:** Consider benefits and adverse effects
- **Pediatric:** Consider higher or more frequent dosing due to higher clearance
- **Geriatric:** Subjects >65yrs not included in study

Contraindications

- Hamster protein sensitivity

Warnings/Precautions

- **Confirm** Factor VIII deficiency prior to treatment
- **Monitor** for development of Factor VIII inhibitors
- **Discontinue** if hypersensitivity reactions occur; consider premedication with antihistamines if previous history of hypersensitivity

Adverse Reactions

- Dizziness
- Hypersensitivity
- Paresthesia
- Rash
- Erythema
- Pruritus
- Pyrexia
- Injection site pain
- Chills
- Feeling hot

Mechanism of Action

- Afstyla is a recombinant protein that replaces the missing coagulation Factor VIII that is needed for effective hemostasis

- It is a single polypeptide chain with a truncated B-domain that allows for a covalent bridge to link the Factor VIII heavy and light chains

Clinical Trials

- The safety and efficacy of Afstyla were evaluated in 2 clinical studies:
  - Open-label, multicenter, crossover safety, efficacy, and pharmacokinetic study in adults/adolescents
  - Open-label pharmacokinetic, efficacy, and safety study in children

Clinical Trials

- The **adult/adolescent** study included 175 previously treated male subjects with severe hemophilia A
  - 174 of 175 subjects received at least 1 dose of Afstyla and 173 were evaluable for efficacy
- The **pediatric** study included 84 previously treated male subjects with severe hemophilia A
  - All 84 subjects received at least 1 dose of Afstyla and 83 were evaluable for efficacy

Clinical Trials

- The **adult/adolescent** study had a total of 848 **bleeding episodes** treated with Afstyla and 835 received an efficacy assessment by the investigator
  - **686** episodes (81%) were controlled with a single Afstyla injection
  - **107** episodes (13%) were controlled with 2 injections
  - **55** episodes (6%) required 3 or more injections
- Efficacy ratings for 94% of the bleeding episodes were “Excellent “or “Good”

Clinical Trials

- The **pediatric** study had a total of 347 **bleeding episodes** treated with Afstyla
- All received an efficacy assessment by the investigator
  - **298** episodes (86%) were controlled with a single Afstyla injection
  - **34** episodes (10%) were controlled with 2 injections
  - **15** episodes (4%) required 3 or more injections
- Efficacy ratings for 96% of bleeding episodes were rated “Excellent” or “Good”

Clinical Trials

- In the **adult/adolescent** study evaluating **routine prophylaxis**, 54% of the 146 subjects on prophylaxis received Afstyla 3 times weekly; 32% received Afstyla twice weekly; 6% received Afstyla every other day; and 8% received other regimens
- The **annualized bleeding rate** (ABR) was comparable between subjects on a 3 times weekly vs. 2 times weekly regimen (1.53 vs. 0.00)
- 43% of subjects experienced no bleeding episodes while on prophylaxis

Clinical Trials

- In the **pediatric** study evaluating **routine prophylaxis**, 54% of the 80 subjects on prophylaxis received Afstyla 3 times weekly, 4% received Afstyla every other day, and 12% of subjects received other regimens
- **Overall ABR** was 3.69, with median ABR 2.3 for subjects on a 3 times weekly regimen vs. 4.37 for subjects on a twice weekly regimen
- 26% of subjects experienced no bleeding episodes while on prophylaxis

Clinical Trials

- In the **adult/adolescent** study evaluating **perioperative management** of bleeding, 13 subjects underwent 16 total procedures
- Hemostatic efficacy of Afstyla in perioperative management was rated "Excellent" in 15 surgeries and "Good" in 1 surgery
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/afstyla/drug/34592/