Vonvendi

(von Willebrand factor [recombinant])

New Product Slideshow

MPR

Introduction

- **Brand name:** Vonvendi
- **Generic name:** von Willebrand Factor (recombinant)
- **Pharmacological class:** Clotting factor
- **Strength and Formulation:** 650 IU VWF:RCo, 1300 IU VWF:RCo; per vial; lyophilized pwd for IV inj after reconstitution; preservative-free
- **Manufacturer:** Baxalta
- **How supplied:** Single-use vials—1 (with diluent and supplies)
- **Legal Classification:** Rx

VONVENDI


NDC 0944-7553-02
VONVENDI
von Willebrand factor
(Recombinant)
Single-use vials, lyophilized powder for solution
For Intravenous Administration After Reconstitution Only.
Rx Only
Baxalta

Indications

- On-demand treatment and control of bleeding episodes in adults with **von Willebrand disease (VWD)**

Dosage & Administration

- Give recombinant factor VIII (FVIII) with first infusion if baseline plasma FVIII level <40% or is unknown (see full labeling)
- ≥18yrs:
  - **Minor bleed:** initially 40–50 IU/kg, then every 8–24 hours as needed
  - **Major bleed:** initially 50–80 IU/kg, then 40–60 IU/kg every 8–24 hours for 2–3 days as needed
- Monitor and adjust according to extent and location of bleed
- Max infusion rate: 4mL/min

Considerations for Special Populations

- **Pregnancy:** Give only if clearly needed
- **Nursing mothers:** Consider benefits and adverse effects
- **Pediatric:** <18yrs: not established
- **Geriatric:** Subjects ≥65yrs not included in study

Contraindications

- Hypersensitivity to hamster or mouse proteins

Warnings/Precautions

- Treatment should be supervised by physician
- **Risk of thrombotic events** in patients with known risk factors or an excessive rise in FVIII levels; monitor
- **Discontinue** immediately if severe allergic reactions occur
- Ineffectiveness may indicate antibody formation; monitor and consider alternative therapy

Adverse Reactions

- Generalized pruritus
- Antibody formation

Mechanism of Action

- Vonvendi promotes hemostasis by mediating platelet adhesion to damaged vascular sub-endothelial matrix (eg, collagen) and platelet aggregation, and acts as a carrier protein for FVIII, protecting it from rapid proteolysis
- The binding capacity and affinity of Vonvendi to FVIII in plasma is comparable to that of endogenous VWF, allowing for Vonvendi to reduce FVIII clearance

Clinical Trials

- The hemostatic efficacy of Vonvendi was assessed in a multicenter, open-label trial investigating different dosing strategies with and without recombinant FVIII for on-demand treatment and control of bleeding episodes in adults diagnosed with von Willebrand disease

Clinical Trials

- Bleeding episodes were treated initially with an infusion of Vonvendi and Advate, and subsequently with Vonvendi with or without Advate based on FVIII:C levels
- A total of 193 bleeding episodes were reported in 22 of 37 subjects exposed to Vonvendi
- The **primary efficacy endpoint** was the number of subjects with treatment success for control of bleeding episodes

Clinical Trials

- **Treatment success** was defined as a mean efficacy rating score <2.5 for all bleeding episodes in a subject treated with Vonvendi (with or without Advate) during the trial period

- Secondary efficacy measures were the number of treated bleeding episodes with an efficacy rating of “excellent” or “good”

Clinical Trials

- **1 infusion** per bleed was required in 92.6% of minor bleeds, 67.2% of moderate bleeds, 14.3% of major/severe bleeds, and 100% of unknown severity
- **2 infusions** per bleed were required in 6.6% of minor bleeds, 21.3% of moderate bleeds, and 57.1% of major/severe bleeds
- **3 infusions** per bleed were required in 0.8% of minor bleeds, 9.8% of moderate bleeds, and 28.6% of major/severe bleeds

Clinical Trials

- An **"excellent"** efficacy rating was met for 96.6% of joint bleeds, 83.3% of GI bleeds, 96.9% of genital tract female mucosal bleeds, 97.6% of nasopharyngeal mucosal bleeds, and 100% of mouth and oral cavity mucosal bleeds

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/vonvendi/drug/34604/