

Vonvendi® [von Willebrand factor (recombinant)] - Expanded indication

- On April 17, 2018, <u>Shire announced</u> the FDA approval of <u>Vonvendi [von Willebrand factor (recombinant)]</u> for perioperative management of bleeding in adults (age 18 and older) diagnosed with von Willebrand disease (VWD).
 - Previously, Vonvendi was indicated for on-demand treatment and control of bleeding episodes in adults (age 18 and older) diagnosed with VWD.
- According to the <u>National Hemophilia Foundation</u>, VWD affects up to 1% of the U.S. population, and is the most common bleeding disorder.
- The efficacy of Vonvendi in perioperative management of bleeding was assessed in an open-label trial of 15 patients with VWD who underwent surgery. Patients were allowed the use of Advate [antihemophilic factor (recombinant)] in addition to Vonvendi. Hemostatic efficacy was measured on a 4-point efficacy scale (excellent, good, moderate, and none) where a rating of excellent or good was required to declare the outcome a success.
 - Overall hemostatic efficacy was 100% (90% CI: 81.9%, 100%).
- The most common adverse reactions (≥ 2%) with Vonvendi use were generalized pruritus, nausea, and dizziness.
 - One subject treated with Vonvendi in the perioperative setting developed deep vein thrombosis after undergoing total hip replacement surgery.
- For perioperative management of bleeding, dosage and frequency of Vonvendi must be individualized according to clinical judgement, weight, type and severity of the bleeding episodes/surgical intervention, and clinical and laboratory measures.
- Refer to the Vonvendi prescribing information for full dosing information for both indications.



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