Voluntary Market Withdrawal

January 26, 2024

Dear Valued Patient,

The purpose of this letter is to inform you that Takeda, in agreement with the U.S. Food and Drug Administration (FDA), has decided to conduct a voluntary market withdrawal for two product lots of 650 IU VONVENDI® [von Willebrand factor (recombinant)] in the U.S. with immediate effect. This withdrawal is being conducted out of an abundance of caution due to misprinted product labels with the incorrect expiration date.

There is no quality issue with VONVENDI. The safety and efficacy profile of VONVENDI remains consistent with the therapy's FDA-approved Prescribing Information. The expiration date printed on the label on the outside of the VONVENDI package (June 27, 2025) is six months after the actual expiration date (January 27, 2025).

We put patients at the forefront of all that we do. Therefore, we are withdrawing any impacted VONVENDI from the market one year ahead of the expiration date to help ensure patients can continue to administer their VONVENDI as prescribed by their healthcare provider. No other Takeda therapies are impacted in the U.S.

Market Withdrawal Instructions

The impacted lots of VONVENDI are listed below.

Product	Lot Number
650 IU VONVENDI	TVA22004AA
650 IU VONVENDI	TVA22004AB

This voluntary market withdrawal is being carried out to the pharmacy level. Please follow the instructions below and complete the required steps to return any impacted product to your pharmacy provider.

- Please examine any VONVENDI in your possession to identify any impacted lots. You can locate the lot number on the outside of the product packaging (see image below).
- **If you have impacted VONVENDI in your possession, please discontinue use immediately and contact your pharmacy provider to request instructions on how to return and replace any impacted product.**
- If you have further questions, please contact your pharmacy provider or prescribing health care provider directly.

Reporting Adverse Events
Health care providers and patients are encouraged to report adverse reactions and/or quality problems related to VONVENDI to Takeda at 1-877-TAKEDA-7 (1-877-825-3327). You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Medical Information
You may also contact our medical information department at 1-877-TAKEDA-7 (1-877-825-3327) or visit www.VONVENDI.com if you have any questions about the information contained in this letter or the safe and effective use of VONVENDI.

Sincerely,

Cheryl Schwartz
Senior Vice President, U.S. Rare Disease Business Unit
Takeda Pharmaceuticals U.S.A.

Enclosure: VONVENDI Full Prescribing Information

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