

### What is **VONVENDI?**

VONVENDI is used in adults (age 18 years and older) diagnosed with von Willebrand disease to:

- treat and control bleeding episodes
- prevent excessive bleeding during and after surgery

#### **Selected Important Risk Information**

Who should not use VONVENDI?

You should not use VONVENDI if you:

- Are allergic to any ingredients in VONVENDI.
- Are allergic to mice or hamsters.

Tell your healthcare provider if you are pregnant or breastfeeding because VONVENDI may not be right for you.

Please see additional Important Risk Information throughout this brochure.

Please see important facts on pages 12 and 13 and click here for full Prescribing Information, and talk to your healthcare provider.



## WHAT IS VON WILLEBRAND DISEASE (VWD)?



VWD is an inherited bleeding disorder that makes it difficult to form blood clots, resulting in more frequent bleeding and bleeds that last longer than normal.

Follow Erica as she moves through her day.



### WHAT CAUSES VWD?



### VWD is caused by either:

- Not having enough von Willebrand factor (VWF)
- Having VWF that isn't working properly

### VWF helps the blood in your vessels clot in two ways:

- 1 VWF acts like glue to help platelets (blood-clotting cells) stick together and form a platelet plug at the site of the wound.
- 2 VWF also stabilizes, protects, and carries the factor VIII (FVIII) that you have in your body to the site of the injury (FVIII is another important protein that helps in clotting blood).

In order to form blood clots that stop bleeding, your body needs the right amount of functional VWF and FVIII.

There are different types of approved treatments that can be used to treat VWD bleeds depending on your individual situation, including those that do not involve factor replacement. Always discuss the most appropriate treatment type for you with your healthcare provider.



## A DECIDING FACTOR FOR VWD

As an adult living with von Willebrand disease (VWD), you may share a bleeding disorder with others, but you have your own life, and your own needs. You may also have your own Deciding Factor—something that drives you to talk to your healthcare provider about finding a treatment that's right for you.

One example is Erica, who raises and homeschools her three children, teaches English classes online, and cares for her mother—all while maintaining a beautiful home and enjoying an active social life. When Erica saw that frequent bleeding episodes were taking time away from the things that mattered most to her, she decided to talk to her healthcare provider. Together, they decided VONVENDI [von Willebrand factor (Recombinant)] was the right treatment to manage Erica's bleeding episodes. Now, Erica knows that when bleeding episodes occur, she has a treatment that works for her.

This brochure can help you decide if it's time to ask your healthcare provider if VONVENDI may be right for you. You may even discover your own Deciding Factor along the way.

### MEET OUR TEAM

Our VWiD Ambassadors represent a vibrant, active community of adults living with different types of VWD who use VONVENDI to help treat and control their bleeding episodes. They share some of the same challenges, but each of their circumstances are as unique as they are.

One thing they have in common? They all had a Deciding Factor that inspired them to talk to their healthcare provider about finding a treatment that was right for them.

Through VWiD, adults living with VWD can attend events to hear from VONVENDI users and Takeda Senior Clinical Specialists. Contact your local National Hemophilia Foundation chapter for more information.



Erica | Surprise, AZ
Diagnosed with VWD in 1981
My Deciding Factor:

Making time for what matters most.



Nicole | Coram. NY

Diagnosed with VWD in 2009

My Deciding Factor:

Making my voice heard.



Leslie | Springfield, MO
Diagnosed with VWD in 2003
My Deciding Factor:
Loving my outdoor lifestyle.

### **Selected Important Risk Information**

How should I use VONVENDI?

Your first dose of VONVENDI for each bleeding episode may be administered with a recombinant factor VIII as instructed by your healthcare provider.

Your healthcare provider will instruct you whether additional doses of VONVENDI with or without recombinant factor VIII are needed.

Please see important facts on pages 12 and 13 and <u>click here</u> for full Prescribing Information, and talk to your healthcare provider.



## HOW DOES THIS TREATMENT WORK?

VONVENDI [von Willebrand factor (Recombinant)] is a von Willebrand disease (VWD) treatment that is infused into your blood stream, where it acts like your body's natural von Willebrand factor (VWF), helping to form clots, and helping your own factor VIII (FVIII) to work.

### VONVENDI: the first and only recombinant VWF for adults with VWD

Recombinant products are manufactured without using human blood. This technology avoids the risk of spreading diseases through infected human blood.

### VONVENDI—created specifically for VWD

VONVENDI is for adults (age 18 and older) diagnosed with VWD, and can be used in two ways:

- To treat and control bleeding episodes as needed, or on-demand
- To prevent excessive bleeding during and after surgery and procedures like tooth extractions and colonoscopies



## USE WITH OR WITHOUT rFVIII, AS DIRECTED

Depending on your specific situation, your healthcare provider will decide if you may use VONVENDI by itself, or if you require additional recombinant FVIII (rFVIII). Whether it's for treating a bleed or managing bleeding during and after surgery, you can work with your healthcare provider to create a dosing plan that works best for you. This will include how and when to infuse VONVENDI, how much VONVENDI you should infuse, whether you might need rFVIII, and any support you may need with mixing and administration.



### Visit <u>VONVENDI.com</u> for more information and resources[,]

[including the instructional video, "A Guide to Self-Infusion"]

### **Selected Important Risk Information**

What should I tell my healthcare provider before I use VONVENDI?

You should tell your healthcare provider if you:

- Have or have had any medical problems.
- Take any medicines, including prescription and non-prescription medicines, such as over-the-counter medicines, supplements or herbal remedies.
- Have any allergies, including allergies to mice or hamsters.
- Are breastfeeding. It is not known if VONVENDI passes into your milk and if it can harm your baby.
- Are pregnant or planning to become pregnant. It is not known if VONVENDI can harm your unborn baby.
- Have been told that you have inhibitors to von Willebrand factor (because VONVENDI may not work for you).
- Have been told that you have inhibitors to blood coagulation factor VIII.

Please see important facts on pages 12 and 13 and <u>click here</u> for full Prescribing Information, and talk to your healthcare provider.



## TREAT AND CONTROL BLEEDING EPISODES ON-DEMAND

VONVENDI
[von Willebrand
factor
(Recombinant)]
can be used
on-demand by
adults with von
Willebrand disease
(VWD) to control
major and minor
bleeds in all

locations, such as:



#### **Mouth bleeds**



Nosebleeds



**Heavy menstrual bleeds** 



Joint bleeds



GI bleeds

"After being trained on how to infuse VONVENDI, I infused my first dose during a particularly heavy period, and I could tell it helped to control the bleeding. I have been taking it for my on-demand needs ever since."

-Erica, VWiD Ambassador



## TESTED IN A CLINICAL TRIAL FOR ON-DEMAND TREATMENT

VONVENDI, given with and without additional rFVIII, was studied in 22 adult patients with different types of severe VWD to test how it would work to control bleeds. The first dose of VONVENDI was given with rFVIII; if further doses were necessary, rFVIII was given only when needed.<sup>a</sup> Investigators rated bleed resolution on a 4-point scale where "Excellent"=1, "Good"=2, "Moderate"=3, and "None"=4. Success was defined as an average score of less than 2.5:

100%

of people had their bleeds successfully treated<sup>b</sup> 96.9%

of 192 bleeds were rated as "Excellent," with the remaining 3.1% rated as "Good" 81.8%

of 192 bleeds were cleared up after just one infusion<sup>a</sup>

### **Selected Important Risk Information**

What else should I know about VONVENDI and von Willebrand disease?

Your body can form inhibitors to von Willebrand factor or factor VIII. An inhibitor is part of the body's normal defense system. If you form inhibitors, it may stop VONVENDI or factor VIII from working properly. Consult with your healthcare provider to make sure you are carefully monitored with blood tests for the development of inhibitors to von Willebrand factor or factor VIII.

Please see important facts on pages 12 and 13 and <u>click here</u> for full Prescribing Information, and talk to your healthcare provider.



<sup>&</sup>lt;sup>a</sup> Your doctor will decide if you may use VONVENDI by itself, or if you also require rFVIII along with VONVENDI, based on your clinical situation.

<sup>&</sup>lt;sup>b</sup> This analysis excluded 4 of a total of 22 patients who were treated with VONVENDI in the trial.

### MANAGE BLEEDING DURING AND AFTER SURGERY

**VONVENDI Ivon Willebrand** factor (Recombinant)] can be used to manage bleeding both during and after major and minor surgeries and procedures in various locations. including:



Mouth, such as a dental extraction



Nose/throat, such as a nasopharyngoscopy or laryngoscopy



**Female reproductive system, such** as a cyst removal



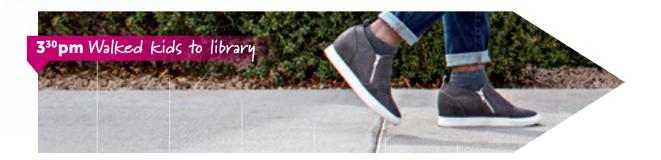
Joint, such as a joint replacement



GI tract, such as a colonoscopy

"In addition to treating and controlling bleeds on-demand. I have also infused VONVENDI to manage bleeding before and after dental surgery, and experienced minimal bleeding. I was convinced."

-Erica. **VWiD Ambassador** 



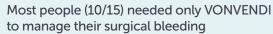
### TESTED IN A CLINICAL TRIAL FOR SURGERIES AND PROCEDURES

VONVENDI was studied in 15 people with all types of severe von Willebrand disease (VWD) to test how it would work to prevent excessive bleeding during and after surgery. VONVENDI was first given 12-24 hours before surgery to give time for each person's natural factor VIII (FVIII) to rise. VONVENDI was given again within 1 hour before surgery, either with or without recombinant FVIII (rFVIII), based on level of FVIII. For at least 48 to 72 hours after surgery, VONVENDI was dosed with or without rFVIII every 12-48 hours as needed to control any potential bleeding. Study investigators rated bleeding control as "Excellent." "Good." "Moderate." or "Poor." with success defined as "Excellent" or "Good":

of surgical bleeds (15/15) were managed successfully, with 9/15 rated as "Excellent" and 6/15 rated as "Good"



The amount of blood loss experienced by people in the study was comparable to that of a person without VWD



Your doctor will decide to use VONVENDI with or without rFVIII based on your needs

Want to know if VONVENDI might be right to treat your next bleed or manage bleeding from a surgical procedure? Talk to your healthcare provider to learn more.

#### **Selected Important Risk Information**

What are the possible side effects of VONVENDI?

You can have an allergic reaction to VONVENDI

Call your healthcare provider right away and stop treatment if you get a rash or hives, itching, tightness of the throat, chest pain or tightness, difficulty breathing, lightheadedness, dizziness, nausea or fainting.

Side effects that have been reported with VONVENDI include: nausea, vomiting, tingling or burning at infusion site, chest discomfort, dizziness, hot flashes, itching, high blood pressure, muscle twitching, unusual taste, blood clots and increased heart rate.

Tell your healthcare provider about any side effects that bother you or do not go away.

Please see important facts on pages 12 and 13 and click here for full Prescribing Information, and talk to your healthcare provider.



### Important facts about VONVENDI®:

This leaflet summarizes important information about VONVENDI. Please read it carefully before using this medicine. This information does not take the place of talking with your healthcare provider.

#### What is VONVENDI?

VONVENDI is a recombinant medicine used to replace low levels or not properly working von Willebrand factor in people with von Willebrand disease. Von Willebrand disease is an inherited bleeding disorder in which blood does not clot normally.

VONVENDI is used in adults (age 18 years and older) diagnosed with von Willebrand disease to:

- Treat and control bleeding episodes
- Prevent excessive bleeding during and after surgery

#### Who should not use VONVENDI?

You should not use VONVENDI if you:

- Are allergic to any ingredients in VONVENDI.
- Are allergic to mice or hamsters.

Tell your healthcare provider if you are pregnant or breastfeeding because VONVENDI may not be right for you.

#### What should I tell my healthcare provider before I use VONVENDI?

You should tell your healthcare provider if you:

- Have or have had any medical problems.
- Take any medicines, including prescription and non-prescription medicines, such as over-the-counter medicines, supplements or herbal remedies.
- Have any allergies, including allergies to mice or hamsters.
- Are breastfeeding. It is not known if VONVENDI passes into your milk and if it can harm your baby.
- Are pregnant or planning to become pregnant. It is not known if VONVENDI can harm your unborn baby.
- Have been told that you have inhibitors to von Willebrand factor (because VONVENDI may not work for vou).
- Have been told that you have inhibitors to blood coagulation factor VIII.

### Important facts about VONVENDI continued:

#### What is the most important information I need to know about VONVENDI?

VONVENDI can cause blood clots particularly in patients with known risk factors for blood clots. Discuss this risk with your healthcare provider.

You can have allergic reactions to VONVENDI. Symptoms may include generalized itching; rash or hives; rapid swelling of the skin or mucous membranes; chest pain or tightness; tightness of the throat; low blood pressure; shock; drowsiness; nausea; vomiting; tingling, prickling, burning, or numbness of the skin; restlessness; wheezing and/or difficulty breathing; lightheadedness; dizziness; or fainting. If symptoms occur, stop using VONVENDI immediately and get emergency treatment right away.

Your body can form inhibitors to von Willebrand factor or factor VIII. An inhibitor is part of the body's normal defense system. If you form inhibitors, they may stop VONVENDI or FVIII from working properly. Consult with your healthcare provider to make sure you are carefully monitored with blood tests for the development of inhibitors to von Willebrand factor or factor VII

### What are the possible side effects of VONVENDI?

Side effects that have been reported with VONVENDI include: nausea, vomiting, tingling or burning at infusion site, chest discomfort, dizziness, hot flashes, itching, high blood pressure, muscle twitching, unusual taste, blood clots and increased heart rate. These are not all the possible side effects with VONVENDI You can ask your healthcare provider for information that is written for healthcare professionals.

Tell your healthcare provider about any side effects that bother you or do not go away.

#### What else should I know about VONVENDI and von Willebrand Disease?

Consult with your healthcare provider to make sure you are carefully monitored with blood tests to measure levels of von Willebrand factor and factor VIII so they are right for you.

You may infuse VONVENDI at a hemophilia treatment center (HTC), at your healthcare provider's office or in your home. You should be trained on how to do infusions by your healthcare provider or HTC. Many people with von Willebrand disease learn to infuse VONVENDI by themselves or with the help of a family member.

Call your healthcare provider right away if your bleeding does not stop after taking VONVENDI.

Medicines are sometimes prescribed for purposes other than those listed here. Do not use VONVENDI for a condition for which it is not prescribed. Do not share VONVENDI with other people, even if they have the same symptoms that you have.

The risk information provided here is not comprehensive. To learn more, talk with your healthcare provider or pharmacist about Vonvendi. The FDA approved product labeling can be found at https://www.shirecontent.com/PI/ PDFs/VONVENDI\_USA\_ENG.pdf or call 1-800-828-2088.

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.

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That's another day in the books for Erica. Like others living with von Willebrand disease (VWD), bleeds are part of her life. With VONVENDI [von Willebrand factor (Recombinant)], Erica knows that when a bleed occurs, she has a treatment that can work for her.



### **Selected Important Risk Information**

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### FOR ADULTS WITH VWD, TAKEDA IS ON YOUR TEAM

Takeda has created a variety of programs to help adults living with VWD throughout their treatment journey:



### Takeda's FREEDOM OF CHOICE™ Free Trial Program

Ask your healthcare provider if you may be eligible to receive 3 free doses of VONVENDI. This Free Trial Program is for new VONVENDI patients only. Participants must receive consultation and approval from a healthcare provider.

### **Stay Connected**

Visit <u>VONVENDI.com/sign-up</u> to receive the latest updates on VONVENDI and further information for the VWD community.

Visit <u>VONVENDI.com</u> to learn more about these programs.



### **HSC Product Support**

Takeda's Hematology Support Center (HSC) is a dedicated team here to help patients who have been prescribed VONVENDI with information, guidance, and resources regarding their treatment.

### **CoPay Assistance**

For eligible commercially insured Takeda patients, Takeda's CoPay assistance program may cover out-of-pocket expenses related to a patient's VONVENDI treatment for which there is a co-pay, such as deductibles and coinsurances, up to the program maximum.

Visit <u>hematologysupport.com</u> or call **1-888-229-8379** to learn more about these programs and other HSC offerings.

# ARE YOU READY TO ASK ABOUT VONVENDI FOR YOUR VWD?

- Is used in adults (age 18 years and older) diagnosed with von Willebrand disease (VWD) to treat and control bleeding episodes and prevent excessive bleeding during and after surgery
- May be taken with or without recombinant factor VIII (rFVIII), depending on your specific situation—your healthcare provider will decide if you can take VONVENDI by itself or if you need rFVIII too
- Is the first and only recombinant VWF, meaning it is manufactured without human plasma or blood

### **Selected Important Risk Information**

Who should not use VONVENDI?

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To learn more about VONVENDI, visit VONVENDI.com.

