wilate®

von Willebrand Factor/Coagulation Factor VIII Complex (Human)

THE **ONLY VWF CONCENTRATE APPROVED** for **ROUTINE PROPHYLAXIS** in children ≥6 years of age and adults in **ALL TYPES** of **VWD**

TAKE CONTROL OF VWD

EDUCATIONAL GUIDE for Patients, Parents, & Caregivers

Indications and Usage

wilate® is a von Willebrand Factor/Coagulation Factor VIII Complex (Human) indicated in children and adults with von Willebrand disease (VWD) for on-demand treatment and control of bleeding episodes; for perioperative management of bleeding; and for routine prophylaxis to reduce the frequency of bleeding episodes in children 6 years of age and older and adults with VWD. wilate is also indicated in adolescents and adults with hemophilia A for routine prophylaxis to reduce the frequency of bleeding episodes; and for on-demand treatment and control of bleeding episodes.

Please see enclosed full Prescribing Information.

octapharma

UNDERSTANDING VWD

Von Willebrand disease (VWD) is an inherited bleeding disorder caused by problems with a protein in the blood called **von Willebrand factor (VWF)**, which affects clotting. VWF also carries and protects **factor VIII (FVIII)**, another important protein that helps blood to clot.[1]

Types of VWD[1-3]

Type 1 VWD

Most common—60%-80% of cases. In type 1 VWD, there is a partial lack of VWF in the blood. The severity of bleeding in type 1 VWD can vary.

Type 2 VWD

Second-most common—15%-30% of cases with several subtypes (2A, 2B, 2M, and 2N). In type 2 VWD, there is a defect in the VWF produced in the blood. There may be normal levels of VWF, but it is unable to function correctly. The type and frequency of bleeding often depends on the subtype.

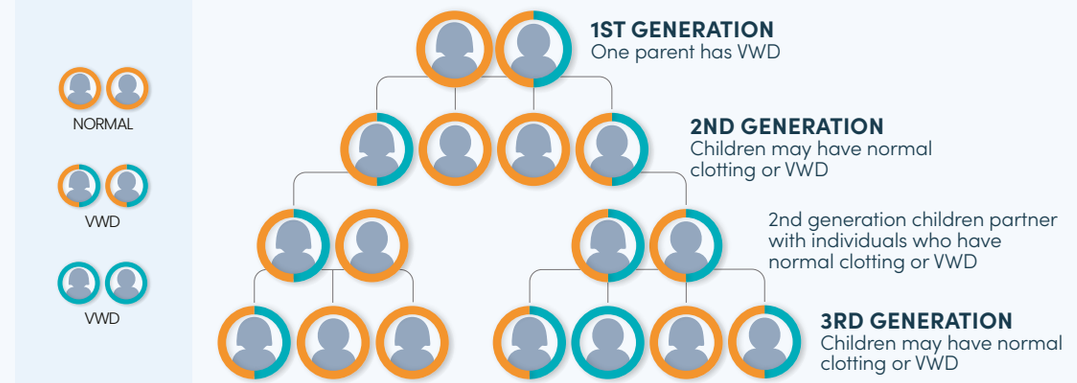
Type 3 VWD

Rarest type—5%-10% of cases. In type 3 VWD, the body is unable to make VWF. Type 3 VWD is the most severe form of VWD. Bleeding can be heavy and frequent.

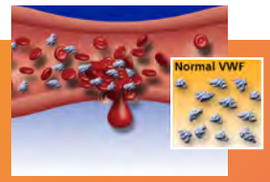
Genetics of VWD[4]

VWD occurs equally in men and women, and is usually inherited, with the parents passing the gene to their children.

Three Generations of a Family With VWD

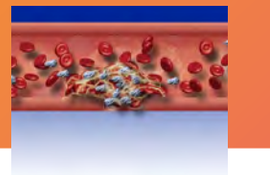


VWF and FVIII Are Both Important for Bleeding Control[5,6]



NORMAL CLOTTING[4]

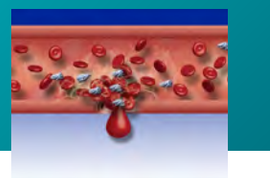
- Damaged blood vessel tightens to slow the flow of blood out of the vein
- Platelets stick to the inside of the blood vessel and plug holes at the injury site



- VWF acts as a "glue," holding the platelets in place at the site of injury so blood can clot
- FVIII helps to form a thick fibrin mesh that holds the clot in place

HOW VWD AFFECTS CLOTTING[4]

- Low levels or nonfunctioning VWF cannot hold the platelets in place, so clotting is impaired



- When VWF is low, so is FVIII, and a solid clot takes a very long time to form

Bleeding Symptoms of VWD[2,4]

Bleeding in VWD ranges from mild to severe. Bleeds can be caused by injury, surgery, or childbirth or they can be "spontaneous" with no apparent cause. Bleeding can occur anywhere in the body.

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How VWD Is Diagnosed[2,4,6]

To diagnose VWD, your doctor will review your personal and family history of bleeding.
Tests that a doctor can order to diagnose VWD include:

- **VWF and FVIII.** To measure the amount of clotting factors and activity in the blood
- **Ristocetin cofactor test or Gp1BM activity.** To measure how well the VWF works
- **VWF multimers.** To measure the makeup or structure of the VWF
- **Platelet aggregation tests.** To measure how well the platelets are working

VWD Treatments[2,4,6]

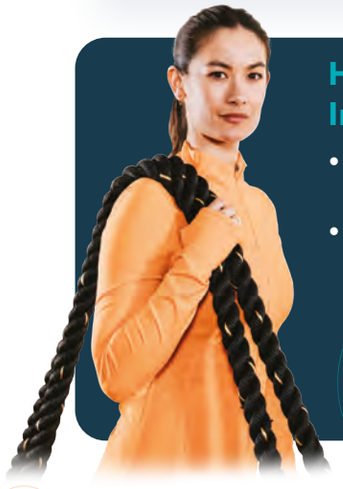
Desmopressin (DDAVP) is a synthetic hormone that stimulates the body to release VWF and factor VIII

Clotting factor concentrates made with purified VWF and/or FVIII to replace the factor in the blood to promote clotting

Antifibrinolytics, such as tranexamic acid, reduce bleeding by slowing the breakdown of clots

Fibrin sealants create a fibrin "net" to help hold platelets together in a clot

Hormones (oral, implantable, injectable, or absorbable) reduce heavy menstrual bleeding by increasing VWF and FVIII levels. Intrauterine devices (IUDs) are also used to reduce heavy menstrual bleeding by releasing progesterone



Heavy Menstrual Bleeding (HMB) and Iron Deficiency in Women With VWD

- Up to **90% of women** with VWD experience heavy menstrual bleeding, which can lead to symptomatic **iron deficiency anemia**[7]
- Current hormonal and many nonhormonal therapies are limited by ineffectiveness and intolerance[8]

VWF + FVIII

Heavy menstrual bleeding may result in iron deficiency anemia. **Treatment with VWF/FVIII concentrate has been shown to reduce HMB.**[9]

Please see enclosed full Prescribing Information.

wilate Offers a Number of Unique Features vs Other VWD Products[10-14]

	wilate®	Humate-P®	Alphanate®	Vonvendi®
Developed specifically for VWD	**YES**	NO	NO	YES
Approved for routine prophylaxis in all types of VWD in children ≥6 years and adults	**YES**	NO	NO	Adults only
Approved for on-demand & surgery in all types of VWD in children ≥6 years and adults	**YES**	YES	NO Surgery only Type 1 or 2 only	YES
Treats all types of bleeds Minor, major, traumatic, spontaneous, surgical	**YES**	YES	NO Surgery only	YES
Balanced 1:1 VWF/FVIII ratio Similar to natural VWF/FVIII in the body	**YES**	NO	Varies by lot	VWF only Supplemental FVIII may be required
Preservative Free No albumin added as stabilizer	**YES**	NO	NO	YES
High Purity	**YES**	NO Intermediate	NO Intermediate	YES Recombinant

Humate-P® is a registered trademark of CSL Behring GmbH. Alphanate® is a registered trademark of Grifols. Vonvendi® is a registered trademark of Takeda.

NOTE: Presentation of Humate-P®, Alphanate®, and Vonvendi® information is not intended to claim or imply inferiority, equivalence, or superiority to wilate in efficacy, safety, or other conditions of use.

Is Routine Prophylaxis Right for Me?

Prophylaxis in VWD involves regular (or routine) administration of VWF concentrates to **prevent** bleeding. People with severe VWD who receive regular prophylaxis have a lower disease burden compared to on-demand treatment, including fewer bleeds (including less menstrual bleeding), less pain and joint damage, and a lower risk of iron deficiency and anemia.[15-17]

Updated guidelines for VWD now recommend routine, long-term prophylaxis with a VWF concentrate to prevent bleeding in adults and children with severe VWD symptoms.[18]

Contraindications
wilate is contraindicated in patients with known hypersensitivity reactions, including anaphylactic or severe systemic reactions, to human plasma-derived products, any ingredient in the formulation, or components of the container.

Please see enclosed full Prescribing Information.

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ROUTINE PROPHYLAXIS

Enhancing the Standard of Care

wilate is the **ONLY** VWF concentrate approved for **routine prophylaxis** to prevent bleeds in **all types** of VWD—in children 6 years and older, adolescents, and adults.

Routine Prophylaxis With wilate Significantly Reduced Bleeding vs Prior On-Demand Treatment[9,10,19*]

PROPHYLAXIS REGIMEN | wilate 20-40 IU/kg infused 2 to 3 times per week for 12 months

*Results of the WIL-31 study, a phase 3 trial conducted in 33 adults and children (6 years) with severe VWD. Results for total bleeds was for the mean reduction in annualized bleeding rate (ABR) vs previous on-demand treatment, which was the primary endpoint. Results for secondary endpoints, spontaneous, nose, joint and menstrual bleeds, were reduction in mean ABRs vs previous on-demand treatment.

Almost a third of patients had **ZERO** total bleeds during wilate prophylaxis and more than half of patients had **ZERO** treated spontaneous bleeds[9,10]

- **84%** of bleeds that occurred were minor
- **99%** of treated bleeds were rated "excellent" (90%) or "good" (9%)
- **87%** of treated bleeds were managed with 1 or 2 infusions

SAFETY & TOLERABILITY: No serious treatment-emergent AEs related to the study drug and no thrombotic events were detected during 12 months of wilate prophylaxis.[9,10]

Warnings and Precautions

Hypersensitivity Reactions

Hypersensitivity reactions may occur with wilate. Signs and symptoms include angioedema, burning and stinging at the infusion site, chills, flushing, generalized urticaria, headache, hives, hypotension, lethargy, nausea, restlessness, tachycardia, tightness of the chest, tingling, vomiting, and wheezing that may progress to severe anaphylaxis (including shock) with or without fever.

Please see enclosed full Prescribing Information.

REAL PATIENTS
Taking Control → Staying *ahead* of bleeding

SARA C | Twin daughters with Type 2 VWD

Parent and Caregiver • Octapharma Patient Educator

SCAN THE CODE TO READ MORE ABOUT SARA

- Her daughters tried several medications to treat their VWD, including Stimate® nasal spray, Humate-P®, and Alphanate® with unsatisfactory results
- Sara wanted proactive protection. She asked her hematologist to prescribe wilate. She now infuses her daughters with wilate at home

"In my research, I discovered wilate, and was attracted to the 1:1 balance of FVIII and VWF...

Based on my family's factor levels, it made sense to me that wilate would be a good fit. Eventually I was able to enroll my daughters in a free product trial. Wilate has performed beautifully for us."

"I am a caregiver and I approach VWD from that standpoint. I do everything I can to get the word out about VWD, bleeding disorders, & caregiving—at school, at church, in my community, and online. I knew nothing about any of this until 10 years ago—now I am committed to raising awareness."

Disclaimer: The views and opinions expressed in this testimonial are those of the caregiver and do not necessarily reflect the opinions or recommendations of Octapharma USA. Results vary from patient to patient.

Stimate® is a registered trademark of Ferring Pharmaceuticals.

Warnings and Precautions

Hypersensitivity Reactions (continued)

Closely monitor patients receiving wilate and observe for any symptoms throughout the infusion period.

Because inhibitor antibodies may occur concomitantly with anaphylactic reactions, evaluate patients experiencing an anaphylactic reaction for the presence of inhibitors.

Please see enclosed full Prescribing Information.

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LOW AND LESS FREQUENT DOSING

Any Patient, Any Type of Bleed, Any Type of VWD

LOADING DOSE | You may be able to lower the initial dose (also called the **loading dose**) you need for the treatment of minor and major bleeds.[10,12]

MAINTENANCE DOSE | You may also be able to increase the amount of time between your doses for bleeds that require multiple doses (also called the **maintenance dose**).[10,12]

wilate®[10]

Bleed severity	Loading dose	Maintenance dose
Minor	20-40 IU/kg	20-30 IU/kg every 12 to 24 hours up to 3 days
Major	40-60 IU/kg	20-40 IU/kg every 12 to 24 hours up to 5-7 days

Humate-P®[12]

Bleed severity	Loading dose	Maintenance dose
Minor	40-60 IU/kg	40-50 IU/kg every 8 to 12 hours for 3 days, then daily for 7 days
Major	**Type 1:** 50-75 IU/kg **Type 2/type 3:** 60-80 IU/kg	40-60 IU/kg every 8 to 12 hours for 3 days, then daily up to 7 days

53% lower dosing with wilate

In separate VWD studies, **wilate dosing was 53% lower than Humate-P** for on-demand treatment (26 IU vs 55 IU)[20,21]

NOTE: Presentation of Humate-P® information is not intended to claim or imply inferiority, equivalence, or superiority to wilate in efficacy, safety, or other conditions of use.

Warnings and Precautions

Thromboembolic Events

In VWD, continued treatment using a FVIII-containing VWF product may cause an excessive rise in FVIII activity, which may increase the risk of thromboembolic events. Monitor plasma levels of VWF:RCo and FVIII activities in patients receiving wilate to avoid sustained excessive VWF and FVIII activity levels.

Please see enclosed full Prescribing Information.

REAL PATIENTS Taking Control → Low dosing, *expanded living*

KERRI B | Severe Type 3 VWD

Pediatric Nurse • Avid Runner

SCAN THE CODE TO READ MORE ABOUT KERRI

- Switched from Humate-P® to wilate®
- Highly active; treats regularly
- Concerned about joint bleeds
- Now using a much lower dose since switching

*"I was using so much Humate-P to control my bleeding. It was one of the reasons I wanted to switch. Today, I'm using much **less** factor with wilate."*

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Warnings and Precautions

Neutralizing Antibodies (VWD)

Neutralizing antibodies (inhibitors) to FVIII and VWF in patients with VWD, especially type 3 patients, may occur. If a patient develops inhibitor to VWF (or to FVIII), the condition will manifest itself as an inadequate clinical response. Thus, if expected VWF activity plasma levels are not attained, or if bleeding is not controlled with an adequate dose or repeated dosing, perform an appropriate assay to determine whether a VWF inhibitor is present.

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POWERFUL TREATMENT FOR BLEEDS

Mild, Severe, Traumatic, Spontaneous

wilate provides control for bleeds in adults, children, and infants with types 1, 2, or 3 VWD, including all VWD subtypes—anywhere in the body[10,20,22]

Nose | Bruising | Gum | Gastrointestinal | Joint | Menstrual | Muscle | Childbirth

Successful Treatment in a Real World Study of Routine Care With wilate in Adults and Children With VWD[23]

ON DEMAND TREATMENT OF BLEEDING

100% Both patients & investigators rated on-demand treatment with wilate as "successful" in 100% of bleeds

94% Bleed resolution was achieved with 1 or 2 infusions of wilate for 94% of treated bleeds

EFFECTIVENESS IN MENSTRUAL BLEEDING

100% Investigators reported treatment effectiveness in every menstrual bleed treated with wilate

83% Patients rated treatment as successful in 83% of bleeds

Observational, prospective, phase 4 study in 111 patients with VWD enrolled at 31 study centers in 11 countries and followed for up to 2 years. In total, 45% of patients had type 1 VWD, 29% type 2, 18% type 3, and 7% did not have data available. One patient (1%) was later diagnosed with hemophilia A rather than VWD. Patients were 68% female, 32% male, and 37% were children. Most bleeds occurring in real-world practice were nasal (43%) and oral (5%). Most menstrual bleeds were moderate (36%) or severe (46%).

Warnings and Precautions

***Neutralizing Antibodies (VWD)* (continued)**

In patients with antibodies against VWF, VWF is not effective and wilate administration may lead to severe adverse events. Consider other therapeutic options for such patients. Because inhibitor antibodies may occur concomitantly with anaphylactic reactions, evaluate patients experiencing an anaphylactic reaction for the presence of inhibitors.

Please see enclosed full Prescribing Information.

REAL PATIENTS
Taking Control → Bleeding control, *multiplied*

ROBIN L | Mother, and 7 children, with VWD

Informed Protector • Fierce Advocate

SCAN THE CODE TO READ MORE ABOUT ROBIN

- Switched her children to wilate from various treatments, including Amicar®, Humate-P®, Stimate®, and tranexamic acid due to issues with bleeding control and poor tolerability
- Started on wilate during her 7th pregnancy for severe vaginal and rectal bleeding, citing the balanced ratio of VWF and FVIII

"wilate is the best option for my family. I have fought to get prescriptions for wilate [and] to keep a dose of wilate on hand at home for every one of us in case of emergencies. Protecting my kids is a 'no-brainer'."

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Amicar® is a registered trademark of Clover Pharmaceuticals Corp.

Important Safety Information

Transmissible Infectious Agents

wilate is made from human plasma. Because this product is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the variant Creutzfeldt-Jakob disease (vCJD) agent. There is also the possibility that unknown infectious agents may be present in the product. The risk that wilate will transmit viruses has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections, and by inactivating and removing certain viruses during manufacture. Despite these measures, it may still potentially transmit disease.

Please see enclosed full Prescribing Information.

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MANAGING BLEEDING IN SURGERY

Effective Control Without FVIII Accumulation

Success in prevention and treatment of bleeding in major and minor surgeries and in type 3 (severe) VWD[20]*

- **97%** ALL SURGERIES
- **95%** MAJOR SURGERIES
- **100%** TYPE 3 VWD

*Prospective, open-label, multinational study in 28 patients with VWD who underwent 30 surgical procedures.

The Importance of Minimizing FVIII Accumulation

FVIII levels may increase when repeat doses of VWF/FVIII are given, such as before and after surgery, possibly leading to FVIII accumulation. FVIII accumulation can increase the risk of a blood clot, also called a venous thromboembolism (VTE). **No FVIII accumulation or VTEs were reported with wilate in a pivotal clinical trial.[10,22]**

VWF and FVIII Plasma Levels With wilate and Humate-P in Patients Undergoing Surgery[22,24]

wilate No accumulation of FVIII was observed after repeat dosing in VWD patients undergoing surgery[22]

Humate-P FVIII levels may increase after repeat dosing in surgery, potentially increasing the risk of FVIII accumulation[24]

Important Safety Information

Transmissible Infectious Agents **(continued)**

Record the batch number of the product every time wilate is administered to a patient, and consider appropriate vaccination (against hepatitis A and B virus) of patients in regular/repeated receipt of wilate. ALL infections thought by a physician possibly to have been transmitted by this product should be reported by the physician or other healthcare provider to Octapharma USA, Inc., at 1-866-766-4860.

Please see enclosed full Prescribing Information.

REAL PATIENTS
Taking Control → Surgery *and beyond*

SCAN THE CODE TO READ MORE ABOUT ANDREW

ANDREW B | Type 2A VWD (Severe)

Recent Graduate • Sports Lover

- Switched to wilate when undergoing knee surgery
- Learned to self-infuse at home
- No FVIII accumulation during and after surgery
- No major bleeds or injection-site reactions since switching to wilate

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NOTE: Presentation of Humate-P® information on the adjacent page is not intended to claim or imply inferiority, equivalence, or superiority to wilate in efficacy, safety, or other conditions of use.

Important Safety Information

Monitoring and Laboratory Tests

Monitor plasma levels of VWF:RCo and FVIII activities in patients receiving wilate to avoid sustained excessive VWF and FVIII activity levels, which may increase the risk of thromboembolism, particularly in patients with known clinical or laboratory risk factors. Monitor for development of VWF and FVIII inhibitors. Perform assays to determine whether VWF and/or FVIII inhibitor(s) is present if bleeding is not controlled with the expected dose of wilate.

Please see enclosed full Prescribing Information.

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von Willebrand Factor/Coagulation
Factor VIII Complex (Human)

SIMPLE AND CONVENIENT USAGE

wilate Is Available in 2 Vial Sizes, 500, or 1000 IU

- wilate is rapidly dissolved in a small injection volume—to help save time during administration
- **Includes Nextaro® needle-free transfer device**—a quick and easy way to mix wilate with less risk of accidental sticks and a built-in filter for a fast and easy process
- Infusion rate is 2 to 4 mL/minute

Flexible storage, both refrigerated and at room temperature

- Store wilate up to **36 months in a refrigerator** (+2°C to +8°C or 36°F to 46°F) from the date of manufacture
- Within this period, wilate may be stored up to **6 months at room temperature** (maximum of +25°C or 77°F)
- **Once stored at room temperature, wilate must not be returned to the refrigerator**

Nextaro® is a registered trademark of sfm medical devices GmbH.

Warnings and Precautions

Adverse Reactions

The most common adverse reactions to treatment with wilate (≥≥≥≥≥1%) in patients with VWD were hypersensitivity reactions, urticaria, and dizziness. The most common adverse reactions to treatment with wilate (≥≥≥≥≥1%) in
previously treated patients with hemophilia A was pyrexia (fever). Seroconversions for antibodies to parvovirus B19 not accompanied by clinical signs of disease have been observed.

The most serious adverse reactions to treatment with wilate in patients with VWD and hemophilia A are hypersensitivity reactions.

Please see enclosed full Prescribing Information.

factor my way®

Strength, Support and Community for People Living with Bleeding Disorders

Factor My Way Assistance

Financial assistance programs and real world insurance know-how all at your fingertips.

Factor My Way Connection

Meet experts and join our online support community to help you access resources and build relationships.

Factor My Way Events

Join scheduled live and on-demand digital information programs and events.

Factor My Way Learning

Learn-as-you-go, practical informational materials about bleeding disorders, treatment and lifestyle management.

wilate **Free Trial** for patients with VWD

Opportunity for you to try wilate at no cost. Eligible patients can receive a free trial of wilate—shipped directly to you and administered under the supervision of your healthcare provider.

Co-pay assistance

Available through **Factor My Way**, provides eligible patients with significant savings on some of the costs associated with their wilate treatment.

$12,000 | **Potential annual savings on the out-of-pocket costs associated with your Octapharma factor therapy**

Membership in Factor My Way is complimentary and open to anyone over the age of 18 in the USA.

factormyway.com | **855-498-4260**

References: 1. Nichols WL, et al. Haemophilia. 2008;14:171-232. **2.** WFH. What is VWD? 2023. http://www1.wfh.org/publication/files/pdf-1330.pdf **3.** Mannucci PM. N Engl J Med. 2004;351:683-694. **4.** CHS. VWD. Accessed Jan 13, 2020. https://www.hemophilia.ca/von-willebrand-disease **5.** Gale AJ. Toxicol Pathol. 2011;39(1):273-280. **6.** CDC. What is VWD? July 7, 2023. https://www.cdc.gov/ncbddd/vwd/facts.html **7.** ISTH. Examining current practices in the care of pregnant women with low von Willebrand factor/disease. https://www.isth.org/page/VWDreadmore **8.** Ragni MV, et al. Haemophilia. 2016;22(3):397-402. **9.** Sidonio RF, et al. Blood Adv. 2024;8(1):1-13. **10.** wilate® full Prescribing Information. Paramus, NJ: Octapharma; rev 2024. **11.** Octapharma AG, Data on file. **12.** Humate-P® Prescribing Information. CSL Behring; June 2020. **13.** Alphanate® Prescribing Information. Grifols Biologics; November 2022. **14.** Vonvendi® Prescribing Information. Takeda Pharmaceuticals; September 2025. **15.** Miesbach W, Berntorp E. Thromb Res. 2021;199:67-74. **16.** Du P, et al. Clin Appl Thromb Hemost. 2022;28:1-8. **17.** James P, James AH. VWD: gynecologic and obstetric considerations. Accessed November 29, 2023. https://www.uptodate.com/contents/von-willebrand-disease-vwd-gynecologic-and-obstetric-considerations/contributors **18.** Connell NT, et al. Blood Adv. 2021;5(1):301-325. **19.** Boban A, et al. Blood. 2023;142(Supplement 1):5509. **20.** Berntorp E, et al. Haemophilia. 2009;15:122-130. **21.** Lillicrap D, et al. Thromb Haemost. 2002;87:224-230. **22.** Srivastava A, et al. Haemophilia. 2017;23:264-72. **23.** Sholzberg M, et al. TH Open. 2021;5:e264-e272. **24.** Lethagen S, et al. J Thromb Haemost. 2007;5:1420-1430.

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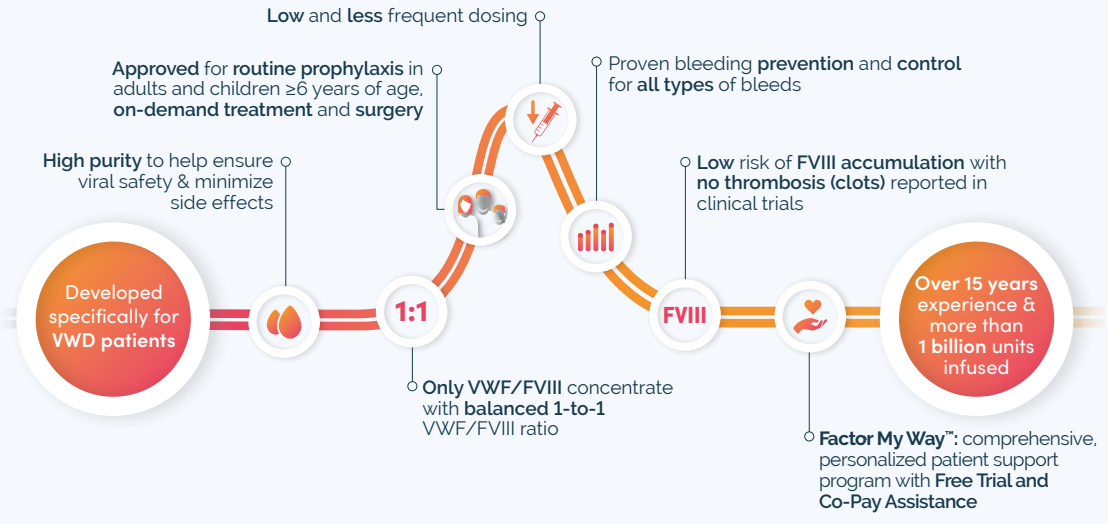
TAKE CONTROL OF VWD



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For all inquiries relating to drug safety, or to report adverse events, please contact our local Drug Safety Officer:
Tel: 201-604-1137 | Cell: 201-772-4546 | Fax: 201-604-1141 or contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Warnings and Precautions

Hypersensitivity Reactions

Hypersensitivity reactions may occur with wilate. Signs and symptoms include angioedema, burning and stinging at the infusion site, chills, flushing, generalized urticaria, headache, hives, hypotension, lethargy, nausea, restlessness, tachycardia, tightness of the chest, tingling, vomiting, and wheezing that may progress to severe anaphylaxis (including shock) with or without fever. Closely monitor patients receiving wilate and observe for any symptoms throughout the infusion period.

Because inhibitor antibodies may occur concomitantly with anaphylactic reactions, evaluate patients experiencing an anaphylactic reaction for the presence of inhibitors.

Please see enclosed full Prescribing Information.

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