octapharma

wilate®
von Willebrand Factor/Coagulation Factor VIII Complex (Human)

Free Trial Request Form

PRESCRIBER INSTRUCTIONS:

Please review and fill out this form in its entirety. This free trial may be redeemed for a one-time trial supply of wilate for up to 3 doses not to exceed 5,000 IU as prescribed for your patient.

If you have questions, please contact the **Factor My Way Support Center** at 1-855-498-4260. Hours of operation are Monday - Friday from 8:30am - 5:00pm EDT.

In order for the free trial request to be fulfilled, you must fax the following to Fortrea at 1-800-554-6744:

- A valid prescription for wilate (von Willebrand Factor/Coagulation Factor VIII Complex [Human]) for the patient indicated below; *and*
- A fully completed **wilate Free Trial Request Form** with both physician and patient/guardian signatures

PRESCRIBER INFORMATION:

Prescriber Name _____ Facility Name _____

Prescriber Address _____ City _____ State _____ Zip _____

State License _____

Phone (___) _____ Fax # (___) _____

NPI # _____

Office Contact Name _____ Email _____
(used to confirm shipment of product)

PATIENT INFORMATION:

Name _____ Contact Phone (___) _____

Patient Address _____ City _____ State _____ Zip _____

Date of Birth _____ Email _____

Language Preference: ☐ English ☐ Spanish ☐ Other _____

Current Therapy _____

PRESCRIPTION INFORMATION:

wilate (von Willebrand Factor/Coagulation Factor VIII Complex [Human])

Available Vial Sizes: 500 IU and/or 1000 IU

Patient Weight: ☐ KG _____ ☐ LB _____

Dose IU/kg _____ Total IU required for one dose of wilate _____

Product to be shipped to: ☐ Prescriber ☐ Patient

Shipping Address _____ City _____ State _____ Zip _____

Additional Prescriber Instructions:

CLEAR FORM

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PROGRAM REQUIREMENTS:

The Octapharma **wilate Free Trial Program** is for a maximum of one trial shipment per patient's lifetime. It is illegal for any person to sell, purchase, or trade; or to offer to sell, purchase, or trade or to counterfeit a **wilate Free Trial** offer. The **wilate Free Trial Program** is valid only for product to be dispensed by a pharmacy designated by Fortrea up to the limits above. Program eligibility does not require any future purchases or orders for wilate and does not require any additional prescription(s) or refills to be filled. Product dispensed pursuant to the terms of the **wilate Free Trial Program** shall not be billed to any patient or third-party payer, public (eg, Medicaid, Medicare, or any other similar federal or state healthcare program) or private. Offer good only in the United States and cannot be combined with any other free trial, coupon, rebate, or similar offer. Octapharma reserves the right to rescind, revoke, or amend this program without notice. The **wilate Free Trial Program** is valid for wilate only—no substitutions permitted. The **wilate Free Trial Program** is good for one fill only and refills will not be authorized. Void where prohibited by law. This is not insurance.

TO BE COMPLETED BY LICENSED PRESCRIBER:

I have read and agree to the terms and conditions of the **wilate Free Trial Program**. In submitting this form, I agree that I will not seek payment from any person or entity for such product. I attest that I have obtained the patient's affirmative authorization to release the above information as may be necessary to Octapharma. If patient is younger than 18 years, I attest that I have obtained authorization from the patient's legal guardian.

Prescriber Signature: _____ Date: _____

The prescriber is to comply with his/her state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Non-compliance with state-specific requirements could result in delay.

PATIENT CONSENT AND HIPAA AUTHORIZATION:

Fortrea is operating the Octapharma **wilate Free Trial Program** and providing services on behalf of Octapharma, in accordance with all applicable HIPAA requirements. I authorize Fortrea to contact my healthcare provider, in order to release and disclose to such parties all relevant medical records, insurance, and third-party payor information, and to send my wilate (von Willebrand Factor/Coagulation Factor VIII Complex [Human]) prescription, via mail, fax, or other mode of delivery, to the specialty pharmacy designated by Fortrea in order to facilitate dispensing of wilate to me. I also authorize my healthcare provider to release and disclose to Fortrea such health information as is necessary to fulfill the above listed purposes. I understand that once information is disclosed it may no longer be protected by federal health information privacy laws and it is possible it may be redisclosed.

☐ I understand that I need to enroll into the **Factor My Way** program to be eligible for the **wilate Free Trial Program**.

Register at www.factorymyway.com or by calling the Factor My Way Support Center at 1-855-498-4260.

Patient Name: _____

Patient Signature: _____

Parent/Guardian (If patient is under 18 years of age): _____

Date: _____

Please fax this 2-page enrollment form and a prescription when completed to Fortrea at 1-800-554-6744

CLEAR FORM

Indications and Usage
wilate® is a von Willebrand Factor/Coagulation Factor VIII Complex (Human) indicated in children and adults with von Willebrand disease for on-demand treatment and control of bleeding episodes and for perioperative management of bleeding. 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.

Important Safety Information

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.

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.

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.

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.

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.

Hemophilia A
Monitor plasma Factor VIII activity by performing a validated test (e.g., one stage clotting assay), to confirm that adequate Factor VIII levels have been achieved and maintained.

Monitor for the development of Factor VIII inhibitors. Perform a Bethesda inhibitor assay if expected Factor VIII plasma levels are not attained, or if bleeding is not controlled with the expected dose of Wilate. Use Bethesda Units (BU) to report inhibitor levels.

Please see accompanying full Prescribing Information for wilate.

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Important Safety Information—continued

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.

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.

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.

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).

Please see accompanying full Prescribing Information for wilate.

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