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

Updated wilate® reconstitution with the convenient and easy-to-use nextaro® transfer device[1-5,a]

Preparing for reconstitution with nextaro is simple[1]

- wilate may be refrigerated[b] for up to 36 months or stored for up to 6 months at room temperature.[c] Do not freeze wilate.
- If stored below room temperature, warm both closed vials by using a warm water bath or rubbing the vials between your hands.[d]
- Inspect all components for physical integrity prior to use. Do not use products or components that appear damaged or broken.
- Reconstitute wilate in a clean environment and minimize contamination.
- Only reconstitute the powder immediately before injection and use the solution within 4 hours.

Please click here to contact your local Patient Experience Manager with any questions

[a]In a usability study, nextaro was preferred over Mix2Vial by healthcare professionals in a clinical setting.[3]
[b]36°F to 46°F (2°C to 8°C).
[c]Not to exceed 77°F (25°C).
[d]If a water bath is used for warming, avoid water contact with the rubber stoppers of the vial caps. The temperature of the water bath should not exceed 98°F (37°C).

Indications and Important Safety Information for wilate® [von Willebrand Factor/Coagulation Factor VIII Complex (Human)].

Indications
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; 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.

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.

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 click here for Full Prescribing Information.

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Reconstitution Is Simple[1]

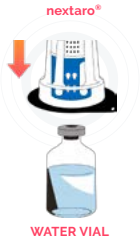
Step 1
Prepare the vials

Remove the caps from the wilate concentrate vial and water vial and clean the rubber stoppers with an alcohol swab.

Step 2
Open nextaro

Open the nextaro transfer device package by peeling off the lid.

Leave the nextaro device in the clear outer packaging and avoid touching the device to keep it clean.



Step 3
Attach nextaro to the water vial

Hold the water vial firmly on a hard, level surface. With nextaro still in the outer packaging, turn it upside down and **push the blue part straight and firmly down on the water vial** until it snaps into place.

Do not twist while attaching.

Note: nextaro must be attached to the water vial first. Otherwise, there will be a loss of suction, and the water will not flow into the wilate vial.

Step 4
Attach the wilate vial

Carefully remove the outer package from the nextaro transfer device.

With the wilate vial held firmly on a hard, level surface, flip the water vial with the attached transfer device upside down and **secure the white part of the transfer device to the wilate vial by pressing on it until it snaps into place.**

The water will be drawn into the wilate vial by the vacuum.

Step 5
Swirl the connected vials

With both vials still attached, immediately start to **gently swirl** the connected vials to ensure that the powder is fully saturated.

Do not shake.

Step 6
Detach nextaro

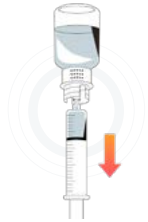
After swirling for 30 seconds, firmly hold the white and blue parts of the nextaro transfer device. Unscrew nextaro counterclockwise into two separate pieces.

Discard the empty water vial and blue part of the transfer device.

Step 7
Continue swirling

Without touching the connector, continue swirling the wilate vial until the powder has fully dissolved. This process may take several minutes.

The final solution is clear or slightly opalescent, colorless, or slightly yellow. Reconstituted products should be inspected visually for particulate matter.



Step 8
Prepare for infusion

Use a syringe to draw out the reconstituted product.

Do not use if the powder fails to dissolve or any solids are formed.

Use/infuse wilate as directed.

Dispose of sharps in their designated location.

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

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, chest discomfort and dizziness. The most common adverse reaction to treatment with wilate® (≥1%) in previously treated patients with hemophilia A was pyrexia (fever).

Please click here for Full Prescribing Information.

References: 1. wilate Full Prescribing Information. Paramus, NJ: Octapharma; rev 2024. **2.** US Food and Drug Administration. 510K Summary: K183187. March 2019. Accessed November 11, 2024. https://www.accessdata.fda.gov/cdrh_docs/pdf18/K183187.pdf **3.** Data on File, Octapharma 2023. **4.** Evolution of transfer systems. sfm medical devices GmbH. Published June 16, 2021. https://www.nextaro.com/en/blog/read/evolution-of-transfer-systems.html **5.** Sustainability and environmental protection through innovative medical products. sfm medical devices GmbH. Published May 15, 2023. https://www.nextaro.com/en/blog/read/sustainability-and-environmental-protection-through-innovative-medical-products.html

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