

Reconstitution Instructions

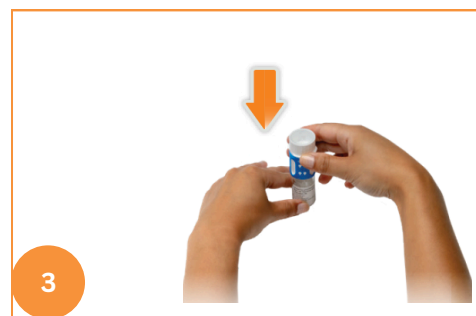
Prepare at room temperature and on a stable surface



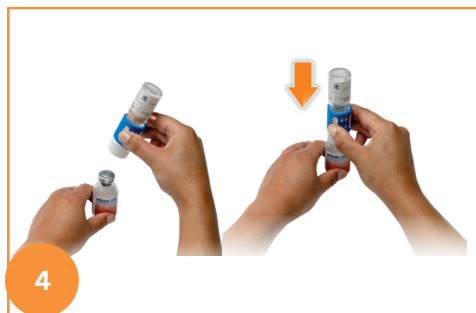
Allow the solvent and the powder in the closed vials to reach room temperature (maximum 37° C). Remove the flip caps from both vials.



Clean the rubber stoppers on both vials with an alcohol swab.



Place the solvent vial on an even surface and hold the vial firmly. Peel away the lid of the Nextaro® transfer device and ensure that it remains in the outer packaging. Then invert it to align the blue water droplet side with the solvent vial. Push Nextaro® straight and firmly down until its blue part snaps into place. **Do not twist while attaching.**



While holding onto the solvent vial, carefully remove the outer package from Nextaro®, being careful to leave it attached firmly to the solvent vial.

With the Wilate® vial held firmly on an even surface, quickly invert the solvent vial (with Nextaro® attached). Place the white part of Nextaro® on top of the Wilate® vial access and press down until it snaps into place. **Do not twist while attaching.** The solvent will be drawn into the Wilate® vial by vacuum.



With both vials still attached, slowly swirl the Wilate® vial to ensure the product is fully dissolved, giving a clear or slightly opalescent, colourless or slightly yellow solution. Once the contents of the Wilate® vial are dissolved, firmly hold both the white and blue parts of Nextaro®. Unscrew it into two separate pieces with the vials still attached and discard the empty solvent vial and the blue part of Nextaro®.



Attach a plastic sterile disposable syringe to the white part of Nextaro®. Invert the system and draw the reconstituted Wilate® into the syringe.



Once the solution has been transferred, firmly hold the barrel of the syringe (keeping it facing down) and detach Nextaro® from the syringe. Discard Nextaro® and the empty Wilate® vial.



Clean the chosen injection site with one of the provided alcohol swabs. Attach a suitable infusion needle to the syringe.

Solution is ready to be injected as instructed.

Inject the solution into the vein at a slow speed of 2–3 mL per minute.

Nextaro® is for single use only.

Strength	Vial Size	Volume of Diluent to be Added to Vial	Approximate Available Volume	Concentration per mL
500 IU	20 mL	5 mL	5 mL	100 IU/mL VWF and 100 IU/mL FVIII
1000 IU	20 mL	10 mL	10 mL	

Administration Instructions	
Description	wilate® is a plasma-derived, stable, highly purified freeze-dried human coagulation VWF/FVIII preparation. The ratio between VWF: RCo and FVIII: C in wilate® is approximately 1:1, which corresponds to the physiological ratio in normal plasma.
Indications and Clinical Use	<p>wilate® is indicated for:</p> <p><u>Hemophilia A</u></p> <ul style="list-style-type: none">• Treatment and prophylaxis of bleeding in patients with hemophilia A (congenital or acquired FVIII deficiency) and for the prevention and treatment of bleeding in minor surgical procedures. <p><u>Von Willebrand disease (VWD)</u></p> <ul style="list-style-type: none">• Treatment and prophylaxis of spontaneous and trauma-induced bleeds in all types of VWD in adult and pediatric patients where use of DDAVP (1-deamino-8-D-arginine vasopressin/desmopressin) treatment is ineffective or contra-indicated.• Prevention and treatment of bleeding during and after surgical procedures
Contraindications	wilate® is contraindicated for patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container.
Storage	<p>wilate® and solvent can be stored at between +2°C and +8°C until the indicated expiry date. Within this period, wilate® and solvent may be stored for a single block of up to 6 months at room temperature (max. +25°C). If stored at room temperature, wilate® must either be used within 6 months or discarded. Protect from light.</p> <p>Do not freeze. The reconstituted solution should be used on one occasion only. Any solution remaining should be discarded.</p>

