Mix2Vial® – The Needleless Transfer System

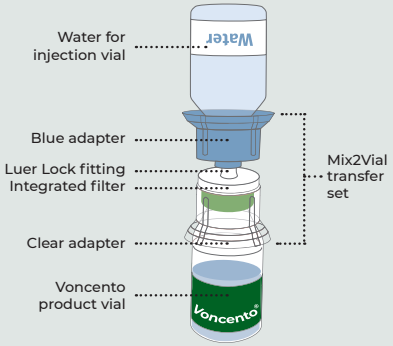
Reduced risk of needle stick injury during reconstitution | Integrated filter

VONCENTO®
(Human Coagulation Factor VIII/
Von Willebrand Factor Complex)

Before you start, disinfect the surface you will be working on and wash your hands thoroughly.

Pay attention to cleanliness and do not touch the connection points of any of the equipment.

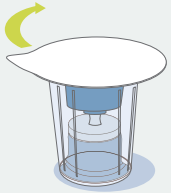
Reconstitution and withdrawal must be carried out under sterile conditions.



How to reconstitute Voncento®

Before you carry out the steps to reconstitute Voncento®, bring the water for injection vial and the product vial to room temperature (below 25°C). Remove the flip caps from both vials and wipe the rubber stoppers with a disinfecting swab. Allow to dry.

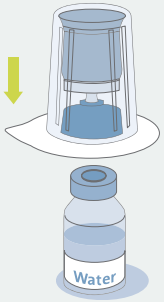
1



Open the Mix2Vial package by peeling off the lid.

Do **not** remove the Mix2Vial from the blister package.

2

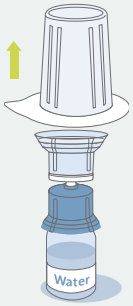


Place the water for injection vial on a clean, hard, flat surface and hold the vial tight.

Take the Mix2Vial together with the blister package and push the spike of the blue adapter **straight down** through the water for injection vial stopper.

The blue adapter locks onto the water for injection vial.

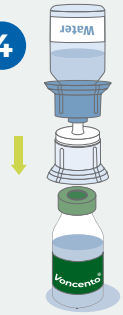
3



Hold onto the water for injection vial and carefully remove the blister package from the Mix2Vial by holding at the rim and pulling **straight upwards** (do not tilt).

Make sure you only pull away the blister package and not the Mix2Vial.

4



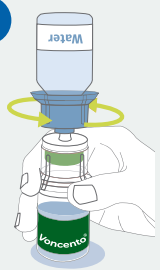
Place the product vial on a clean, hard, flat surface.

Turn the water for injection vial upside down with the Mix2Vial attached and push the spike of the clear adapter **straight down** through the product vial stopper.

It is important that you do not lift the product vial off the flat surface.

The clear adapter locks onto the product vial. The water will automatically flow from the water for injection vial into the product vial.

5



When the water for injection vial is empty, hold the clear adapter (product-vial side of the Mix2Vial) in one hand and the blue adapter (water-vial side) in the other.

Carefully unscrew the Mix2Vial anticlockwise into two pieces.

6

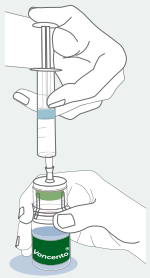
Discard the water for injection vial with the blue adapter attached.

Gently swirl the product vial with the clear adapter attached until the powder is fully dissolved.

Take care not to touch the opening of the adapter, and do not shake.

How to prepare Voncento® for injection

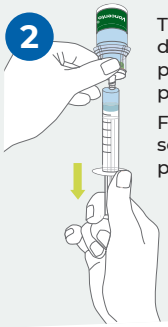
1



Draw air into an empty, sterile syringe (provided in the Voncento® pack). Keeping the product vial upright on a flat surface, connect the syringe to the Mix2Vial's Luer Lock fitting (the white fitting on the clear adapter) by screwing clockwise.

Inject air into the product vial but try not to inject any air into the solution, to avoid foaming.

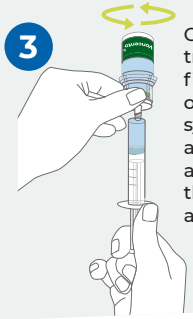
2



Turn the system upside down, keeping the plunger of the syringe pressed in.

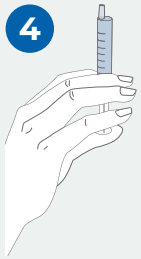
Fill the syringe with the solution by pulling the plunger back slowly.

3



Once the solution has been transferred into the syringe, firmly hold on to the barrel of the syringe (keeping the syringe plunger facing down) and disconnect the clear adapter of the Mix2Vial from the syringe by unscrewing anticlockwise.

4



Point the connector tube of the syringe upwards and expel the air gently from the syringe, being careful not to expel the solution.

If you put the syringe down, make sure that the syringe tip does not touch any surface.

Images are for illustrative purposes only and are not drawn to scale.
Prescribing Information can be found on the back.

GBR-VCT-0106 March 2022

For UK Healthcare Professionals Only

Biotherapies for Life™ CSL Behring

PRESCRIBING INFORMATION: Voncento® (Human coagulation factor VIII/von Willebrand factor complex)

Please refer to the Summary of Product Characteristics (SPC) before prescribing.

Presentation: 500 IU / 1200 IU and 1000 IU / 2400 IU packs of powder and solvent for solution for injection / infusion. **Indications:** Prophylaxis and treatment of haemorrhage or surgical bleeding in patients with VWD, when desmopressin (DDAVP) treatment alone is ineffective or contraindicated. Voncento can be used for all age groups. **Dosage and Administration:** *On-demand treatment:* Usually 40 - 80 IU/kg of von Willebrand factor (VWF:RCo) corresponding to 20 - 40 IU FVIII:C/kg of body weight (BW) are recommended to achieve haemostasis. An initial dose of 80 IU/kg VWF:RCo may be required, especially in patients with type 3. *Long term prophylaxis:* 25 - 40 IU VWF:RCo / kg body weight should be considered at a frequency of 1 to 3 times per week. In patients with gastrointestinal bleeds or menorrhagia, shorter dose intervals or higher doses may be necessary. The dose and duration of treatment will depend on the clinical status of the patient, as well as their VWF:RCo and FVIII:C plasma levels. *Prevention of haemorrhage in case of surgery:* for prevention of excessive bleeding during or after surgery administration should start 1 - 2 hours before the surgical procedure. An appropriate dose should be re-administered every 12 - 24 hours. The dose and duration of the treatment depend on the clinical status of the patient, the type and severity of the bleeding, and both VWF:RCo and FVIII:C levels. *Treatment of bleeding in paediatric patients:* Usually 40 - 80 IU/kg of VWF:RCo corresponding to 20 - 40 IU FVIII:C/kg of body weight (BW) are recommended. *Prophylaxis treatment in patients aged 12 to 18 years:* Dosing is based on the same guidelines as for adults. *Prophylaxis treatment in patients under 12 years:* a dose range of 40 – 80 IU VWF:RCo/kg body weight 1 to 3 times a week should be considered. See SmPC for further dosage information. *Method of administration:* The reconstituted preparation should be injected/infused slowly intravenously at a rate comfortable for the patient not exceeding 6 ml per minute. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Special Warnings & Precautions:** *Traceability:* Name and batch number of the product administered should be recorded. *Hypersensitivity:* Allergic type hypersensitivity reactions are possible. If symptoms occur, patients should be advised to discontinue and contact their physician. Patients should be informed of the early signs of hypersensitivity. In case of shock, the current medical standards for shock treatment should be observed. *Virus safety:* Standard measures used to prevent infections from medicinal products prepared from human blood/plasma are considered effective for enveloped viruses such as HIV, HBV, HCV and the non-enveloped HAV viruses, but may be of limited value against non-enveloped viruses such as parvovirus B19. Appropriate vaccination (hepatitis A and B) should be considered for patients. *von Willebrand disease:* There is a risk of occurrence of thrombotic events, particularly in patients with known risk factors. At risk patients must be monitored for early signs of thrombosis. Prophylaxis against venous thromboembolism should be instituted, according to the current recommendations. When using a FVIII-containing VWF product, the physician should be aware that continued treatment may cause an excessive rise in FVIII:C. which may increase the risk of thrombotic events. Plasma levels of FVIII:C should be monitored and antithrombotic measures considered. Neutralising antibodies(inhibitors) to VWF may develop. If the expected VWF:RCo activity plasma levels are not attained, or if bleeding is not controlled, an appropriate assay should be used to determine if a VWF inhibitor is present. In patients with high levels of inhibitor, therapy may not only be ineffective but also lead to anaphylactoid reactions and, other therapeutic options should be considered. *Cardiovascular events:* In patients with cardiovascular risk factors, therapy with FVIII may increase the cardiovascular risk. *Catheter-related complications:* If a central venous access device (CVAD) is required, risk of complications including local infections, bacteremia and catheter site thrombosis should be considered. *Sodium content:* 500 IU FVIII / 1200 IU VWF presentation contains up to 14.75 mg of sodium. 1000 IU FVIII / 2400 IU VWF presentation contains up to 29.50 mg of sodium. *Paediatric population:* The listed warnings and precautions apply both to adults and paediatrics. **Pregnancy and Lactation:** Administer only if clearly indicated and benefit outweighs risk. **Undesirable Effects:** *Very common (≥1/10)*: headache, FVIII inhibition (PUPs). *Common (≥1/100 to <1/10):* hypersensitivity (including tachycardia, chest pain, chest discomfort and back pain), pyrexia. *Uncommon (≥1/1,000 to <1/100):* FVIII inhibition (PTP), dysgeusia, thromboembolic event, liver function test abnormal. *Not known:* VWF inhibition. Refer to the SPC for details on full side effect profile and interactions. **Marketing authorisation Number:** Voncento 500/1200: PLGB 15036/0158 (EU/1/13/857/003), Voncento 1000/2400: PLGB 15036/0149 (EU/1/13/857/004) NHS **Maximum Price: 500/1200 IU:** £385.00; 1000/ 2400 IU: £770.00. **Further information is available from:** CSL Behring UK Limited, 4 Milton Road, Haywards Heath, West Sussex, RH16 1AH. **Legal Category:** POM. **Date Prepared:** Jan 2022. **PI Approval Code:** GBR-VCT-0100

Adverse events should be reported. Reporting forms and information can be found at **https://yellowcard.mhra.gov.uk/.**

Adverse events should also be reported to CSL Behring UK Ltd. on 01444 447 405

Biotherapies for Life™ CSL Behring

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