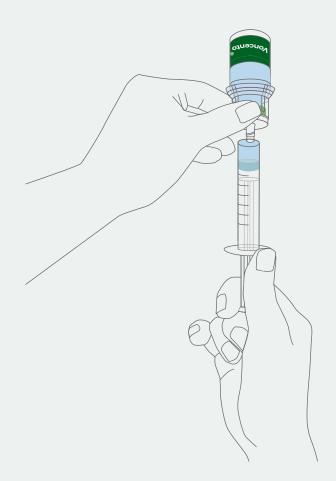
Mix2Vial® – The Needleless Transfer System



Instructions for reconstituting and preparing Voncento®

(Human Coagulation Factor VIII/Von Willebrand Factor Complex)

A guide for patients

This leaflet has been designed for use only by adult patients who have been prescribed Voncento

A Voncento package leaflet can be found inside the Voncento pack. Please read the complete leaflet carefully.



Getting started

Set out all the items you will need and prepare everything together on a clean, hard, flat surface, e.g. on a table.

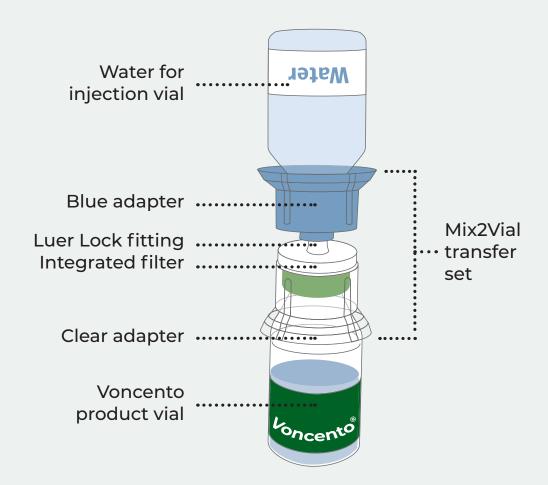
Items for use during reconstitution included in each pack of Voncento:

- Voncento product vial (vial containing powder)
 Do not use after expiry date
- Water for injection vial (vial containing liquid)
 Do not use after expiry date
- Mix2Vial transfer set
- Disposable syringe
- Disinfectant (alcohol) swabs

You will also find included in each pack of Voncento:

- Venipuncture set (including butterfly needle)
- A plaster

Contact your care team if you are unsure about anything.



Your Mix2Vial

- Reduced risk of needle stick injury during reconstitution
- Integrated filter

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 or body temperature – either by leaving the vials at room temperature for about an hour or by holding them in your hands for a few minutes. DO NOT expose the vials to direct heat. The vials must not exceed body temperature (37°C).

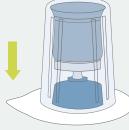
Remove the flip caps from both vials and wipe the rubber stoppers with a disinfecting swab. Allow to dry.





Open the Mix2Vial package by peeling off the lid.

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



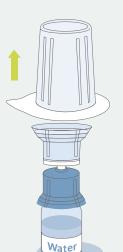




Place the water for injection vial on a clean, hard, flat surface and hold the vial tight.

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.





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.

How to reconstitute Voncento



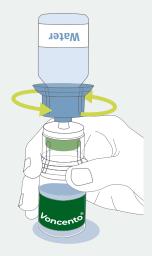


Place the product vial on a clean, hard, flat surface.

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.





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.





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.

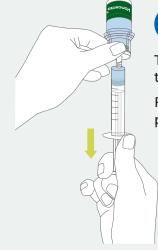
How to prepare Voncento for injection





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.





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.





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.



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.

Reporting side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.