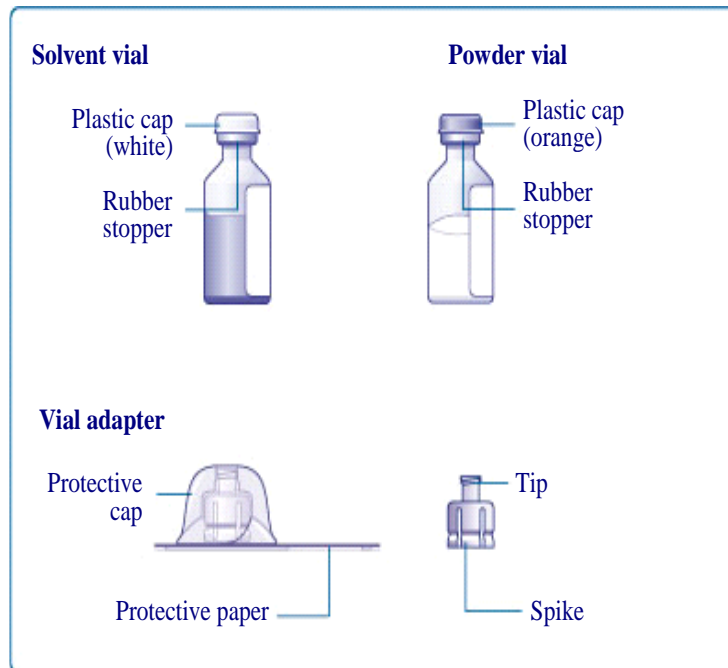

NovoThirteen® Instructions For Use



To reconstitute and administer this product the following tools are needed: a 10 ml syringe or a syringe of convenient size according to the injection volume, alcohol swabs, the included vial adaptor and an infusion set (tubing, butterfly needle).

Preparing the solution

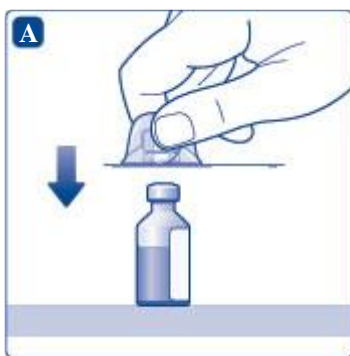
Check the name and the colour of the package to make sure it contains the right product as well as that the product has not passed the expiration date.

Always use an aseptic technique. Before starting, wash your hands. Bring the powder and solvent vials to a room temperature not above 25°C, by holding them in the hands until they feel as warm as your hands. Remove the plastic caps from the two vials. If the caps are loose or missing, do not use the vials. Clean the rubber stoppers on the vials with alcohol swabs and allow them to dry before use. Do not touch the rubber stoppers after wiping them.

A

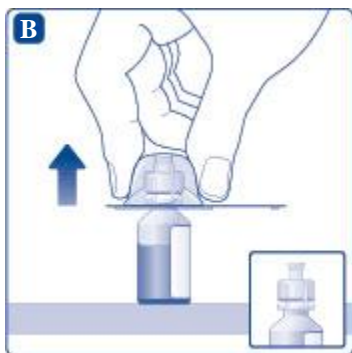
The product is reconstituted using the vial adaptor included.

Remove the protective paper from the vial adaptor without taking the vial out of the protective cap. If the protective paper is not fully sealed, or if it is broken, do not use the vial adaptor. Place the solvent vial on a flat solid place and attach the vial adaptor to the solvent vial (water for injection). Take care not to touch the spike on the vial adaptor.



B

Once attached, remove the protective cap from the vial adaptor by lightly squeezing the protective cap with your thumb and index finger as shown.

**C**

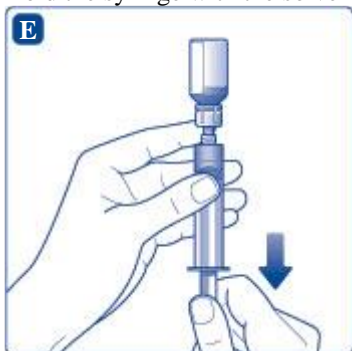
Pull the plunger to draw in a volume of air that is equal to the amount of solvent in the solvent vial (mL equals cc on the syringe).

**D**

Screw the syringe securely onto the vial adaptor on the solvent vial. Inject air into the vial by pushing the plunger until you feel a clear resistance.

**E**

Hold the syringe with the solvent vial upside down. Pull the plunger to draw the solvent into the syringe.



F

Remove the empty solvent vial by tipping the syringe with the vial adaptor.

**G**

Click the vial adaptor, still attached to the syringe, onto the powder vial. Hold the syringe slightly tilted with the vial facing downwards. Push the plunger slowly to inject the solvent into the powder vial. Make sure not to aim the stream of solvent directly at the powder as this will cause foaming.

**H**

Gently swirl the vial until all the powder is dissolved. Do not shake the vial as this will cause foaming.

NovoThirteen[®] should be inspected visually for extraneous (for any foreign) particulate matter and discoloration prior to administration. In the event of either being observed, discard the medicinal product. Reconstituted NovoThirteen[®] is a clear, colourless solution. If a larger dose is needed, repeat the procedure in a separate syringe until the required dose is reached.

**Important Information**

Once prepared, NovoThirteen[®] for injection should be used immediately. This is because the medicine may no longer be sterile. Also the amount of non-proteolytically activated rFXIII in the medicine will increase. Non-proteolytically activated NovoThirteen[®] may increase the risk of getting a blood clot (thrombosis).

If the reconstituted product is not used immediately it should be used within 3 hours and can be stored at room temperature (below 25°C) during this time. Any unused product stored at room temperature for 3 hours should be discarded.

If the reconstituted product is not administered immediately, it should be stored in the refrigerator at 2°C - 8°C for no longer than 24 hours.

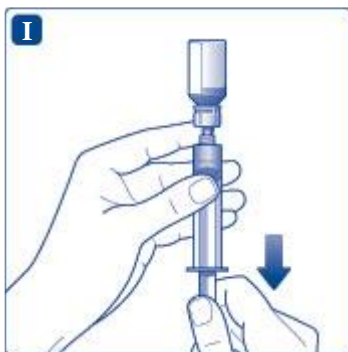
The reconstituted product must not be frozen. If the reconstituted product does become frozen it must not be used and must be discarded.

In case a dilution of the reconstituted NovoThirteen[®] is needed, proceed to the section 'Dilution of the reconstituted product with sodium chloride 0.9%, solution for injection'.

Injecting the solution

I

Ensure that the plunger is pushed all the way in before turning the syringe upside down (it may have been pushed out by the pressure in the vial). Hold the syringe with the vial upside down and pull the plunger to draw up the amount calculated for the injection.

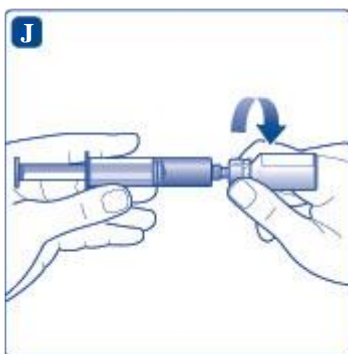


J

Unscrew the vial adaptor with the vial. The product is now ready for injection in the vein. Follow the injection procedure as instructed by your healthcare professional.

Following reconstitution the product should be administered separately and not mixed with infusion solutions nor be given in a drip.

The preparation should be administered as a slow bolus intravenous injection at a rate not higher than 2 mL/minute.



K

Safely dispose of the syringe, vial adaptor, infusion set and vials. Any unused medicinal product or waste material should be disposed of in accordance with local requirements or as instructed by your healthcare professional.



Dilution of the reconstituted product with sodium chloride 0.9%

If dilution of the reconstituted NovoThirteen[®] is necessary in order to be able to handle the dosing of children below 24 kg the reconstituted NovoThirteen[®] should be diluted with 6.0 mL 0.9% sodium chloride (see section 'Using NovoThirteen[®] - Use in small children').

User instruction on how to dilute the reconstituted NovoThirteen[®]

To dilute the reconstituted NovoThirteen[®] the following tools are needed: a vial containing sodium chloride 0.9% solution for injection, a 10 mL syringe, alcohol swabs.

General instruction for dilution

The dilution should be performed in accordance with aseptic rules.

Carefully draw 6.0 mL sodium chloride 0.9%, solution for injection, into the 10 mL syringe.

Slowly inject the 6.0 mL sodium chloride 0.9%, solution for injection, into the reconstituted NovoThirteen[®] vial.

Gently swirl to mix the solution.

The diluted solution is a clear, colourless solution. Check the injection solution for particulate matter and for discolouration. If either is noticed, please discard.

Ask your doctor for advice before the reconstituted NovoThirteen[®] is diluted with sodium chloride 0.9%, solution for injection.