

INSTRUCTIONS FOR PREPARING AND GIVING AN INJECTION OF BENEFIX

Always use BeneFIX exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will decide the dose of BeneFIX you will receive. This dose and duration will depend on your individual needs for factor IX therapy and upon drug pharmacokinetics (recovery and half-life) that have to be checked regularly. You may notice a difference in the dose you receive if you are changing from a plasma-derived factor IX product to BeneFIX.

Your doctor may decide to change the dose of BeneFIX you receive during your treatment.

Reconstitution and administration

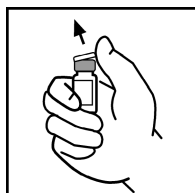
The procedures below are provided as guidelines for the reconstitution and administration of BeneFIX. Patients should follow the specific venipuncture procedures provided by their physicians.

BeneFIX is administered by intravenous (IV) injection after reconstitution of the lyophilised powder for injection with the supplied diluent (0.234% w/v sodium chloride solution) in the pre-filled syringe.

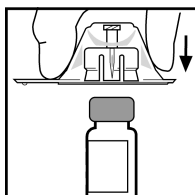
Always wash your hands prior to performing the following procedures. Aseptic technique (meaning clean and germ-free) should be used during the reconstitution procedure.

Reconstitution:

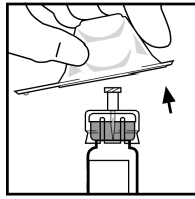
1. Allow the vial of lyophilised BeneFIX and the pre-filled diluent syringe to reach room temperature.
2. Remove the plastic flip-top cap from the BeneFIX vial to expose the central portion of the rubber stopper.



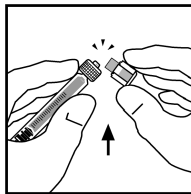
3. Wipe the top of the vial with the alcohol swab provided and allow to dry. After cleaning do not touch the rubber stopper with your hand or allow it to touch any surface.
4. Peel back the lid from the clear plastic vial adapter package. Do not remove the adapter from the package.
5. Place the vial on a flat surface. While holding the adapter in the package, place the vial adapter over the vial. Press down firmly on the package until the adapter snaps into place on top of the vial, with the adapter spike penetrating the vial stopper.



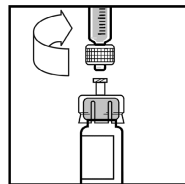
6. Lift the package away from the adapter and discard the package.



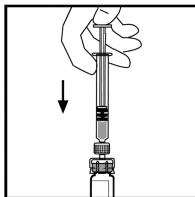
7. Attach the plunger rod to the diluent syringe by pushing and turning firmly.
8. Break off the tamper-resistant plastic tip cap from the diluent syringe by snapping the perforation of the cap. This is done by bending the cap up and down until the perforation is broken. Do not touch the inside of the cap or the syringe tip. The cap may need to be replaced (if not administering reconstituted BeneFIX immediately), so set it aside by placing it on its top.



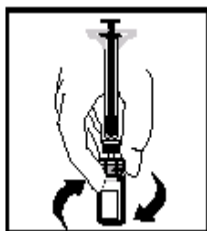
9. Place the vial on a flat surface. Connect the diluent syringe to the vial adapter by inserting the tip of the syringe into the adapter opening while firmly pushing and turning the syringe clockwise until the connection is secured.



10. Slowly depress the plunger rod to inject all the diluent into the BeneFIX vial



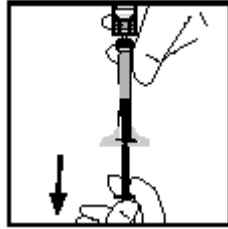
11. With the syringe still connected to the adapter, gently rotate the vial until the powder is dissolved.



12. The final solution should be inspected visually for particulate matter before administration. The solution should appear clear and colourless.

Note: If you use more than one vial of BeneFIX per infusion, each vial should be reconstituted as per the previous instructions. The diluent syringe should be removed, leaving the vial adapter in place, and a separate large luer lock syringe may be used to draw back the reconstituted contents of each individual vial.

13. Ensuring that the syringe plunger rod is still fully depressed, invert the vial. Slowly draw back all the solution into the syringe.



14. Detach the syringe from the vial adapter by gently pulling and turning the syringe counter-clockwise. Discard the vial with the adapter attached.

Note: If the solution is not to be used immediately, the syringe cap should be carefully replaced. Do not touch the syringe tip or the inside of the cap.

BeneFIX should be administered immediately or within 3 hours after reconstitution. The reconstituted solution may be stored at room temperature prior to administration.

Administration (Intravenous injection):

BeneFIX should be administered using the pre-filled diluent syringe provided or a single sterile disposable plastic luer lock syringe. In addition, the solution should be withdrawn from the vial using the vial adapter.

Attach the syringe to the luer end of the infusion set and perform venipuncture as instructed by your physician.

BeneFIX should be injected intravenously over several minutes. Your doctor may change your recommended infusion rate to make the infusion more comfortable.

If you see clumping of red blood cells in the tubing or syringe, discard all this material (tubing, syringe and BeneFIX solution) and start again with a new package.

Because the use of BeneFIX by continuous infusion has not been evaluated, BeneFIX should not be mixed with infusion solutions or be given in a drip.

Please dispose of all unused solution, empty vials, used needles and syringes in a sharps bin.