Vial Adapter Instructions for Use

Always work on a clean surface and wash your hands before performing the following procedure. Use only the components for reconstitution and administration that are provided with each package of Kogenate® FS Antihemophilic Factor (Recombinant). If a package is opened or damaged, do not use any of the components. If the components cannot be used, please contact your healthcare provider. Should you have any questions about Kogenate FS, please contact Bayer at 1-888-84-BAYER (1-888-842-2937).

1. Warm the unopened diluent and the concentrate to a temperature not to exceed 37°C or 99°F.
2. Remove protective cap from the vial (A). Aseptically cleanse the rubber stopper with alcohol, being careful not to handle the rubber stopper.
3. Place product vial on a firm, non-skid surface. Peel off the paper cover on the vial adapter plastic housing. Do not remove the adapter from the plastic housing. Holding the adapter housing, place over the product vial and firmly press down (B). The adapter will snap over the vial cap. Do not remove the adapter housing at this step.
4. Holding the syringe by the barrel, snap the syringe cap off the tip (C). Do not touch the syringe tip with your hand or any surface. Set the syringe aside for further use.
5. Now remove and discard the adapter housing (D).
6. Attach the prefilled syringe to the threaded vial adapter by turning clockwise (E).
7. Grasp the plunger rod by the top plate. Avoid touching the sides and threads of the plunger rod. Immediately attach the plunger rod by turning it firmly clockwise into the threaded syringe rubber stopper (F).
8. Inject the diluent by slowly pushing down on the plunger rod (G).
9. Swirl vial gently until all material is dissolved (H). Do not shake vial. Be sure that the powder is completely dissolved. Do not use solutions containing visible particles or that are cloudy.
10. Withdraw solution into the syringe by holding the vial on end above the vial adapter and syringe (I), then draw the plunger rod out slowly and smoothly. Ensure that the entire content of the vial is drawn into the syringe.
11. With the plunger rod in place, remove the syringe from the vial adapter (the latter should remain attached to the vial). Attach the syringe to the administration set provided and inject intravenously (J). NOTE: Follow instructions for infusion set provided.
12. If the same patient is to receive more than one bottle, reconstitute each bottle with the diluent syringe provided, then combine solutions in a larger syringe (not provided) and administer as usual.

Rate of administration
The entire dose of Kogenate FS can usually be infused within 1 to 15 minutes. However, your healthcare provider will determine the rate of administration that is best for you.

INDICATIONS
- Kogenate® FS Antihemophilic Factor (Recombinant) is a medicine used to replace clotting factor (factor VIII or antihemophilic factor) that is missing in people with hemophilia A.
- Kogenate FS is used to treat and control bleeding in adults and children with hemophilia A. Your healthcare provider may give you Kogenate FS when you have surgery. Kogenate FS can reduce the number of bleeding episodes in adults and children when used regularly (prophylaxis). Kogenate FS can reduce the risk of joint damage in children without pre-existing joint damage when used regularly.
- Kogenate FS is not used to treat von Willebrand disease.

IMPORTANT SAFETY INFORMATION
- You should not use Kogenate FS if you are allergic to rodents (like mice and hamsters) or are allergic to any ingredients in Kogenate FS.
- Tell your healthcare provider if you have been told you have heart disease or are at risk for heart disease.
- You could have an allergic reaction to Kogenate FS. Call your healthcare provider right away if you get rash or hives, itching, tightness of the chest or throat, difficulty breathing, light-headed, dizziness, nausea or a decrease in blood pressure.
- Your body can make antibodies, called “inhibitors,” against Kogenate FS, which may stop Kogenate FS from working properly. Consult with your healthcare provider to make sure you are carefully monitored with blood tests for the development of inhibitors to factor VIII.
- Other common side effects of Kogenate FS are local injection site reactions (pain, swelling, irritation at infusion site) and infections from implanted injection device. Tell your healthcare provider about any side effect that bothers you or does not go away.
- Call your healthcare provider right away if bleeding is not controlled after using Kogenate FS.

For important risk and use information, please see the full Prescribing Information.

You are encouraged to report negative side effects or quality complaints of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.