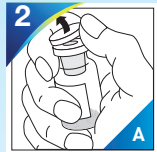
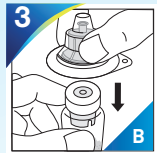

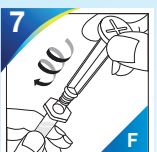
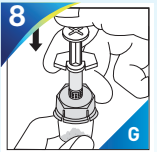

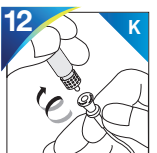


Vial Adapter Instructions for Use



Use only the components for reconstitution and administration that are provided with each package of Jivi®. If a package is opened or damaged, do not use this component. If these components cannot be used, please contact your healthcare provider. Gather all the materials needed for the infusion.

Always work on a clean flat surface and wash your hands before performing the following procedures.

-  **1** Warm the unopened diluent syringe and the concentrate vial 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 a sterile alcohol swab, 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 plastic housing (D).
-  **6** Attach the prefilled syringe to the vial adapter thread by turning clockwise (E).
-  **7** Remove the clear plastic plunger rod from the carton. Grasp the plunger rod by the top plate. **Avoid touching the sides and threads of the plunger rod.** Attach the plunger rod by turning it clockwise into the threaded rubber stopper of the prefilled syringe (F).
-  **8** Inject the diluent **slowly** by pushing down on the plunger rod (G).
-  **9** Swirl vial gently until all powder on all sides of the vial is dissolved (H). **Do not shake vial.** Be sure that all powder is completely dissolved. **Do not use if solution contains visible particles or is cloudy.**
-  **10** Push down on the plunger to push all air back into the vial. Then while holding the plunger down, turn the vial with syringe upside-down (invert) so the vial is now above the syringe (I). Pooling: Pooling is a process of combining the contents of multiple vials into a syringe. If the dose requires more than one vial, reconstitute each vial as described above with the diluent syringe provided. To combine the contents of the vials, use a larger plastic syringe (not provided) to pool the solution into the syringe and administer as usual.
-  **11** Filter the reconstituted product to remove potential particulate matter in the solution. Filtering is achieved by using the vial adapter. Withdraw all the solution through the vial adapter into the syringe by pulling the plunger rod back slowly and smoothly (J). Tilt the vial to the side and back to make sure all the solution has been drawn toward the large opening in the rubber stopper and into the syringe. Remove as much air as possible before removing the syringe from the vial by slowly and carefully pushing the air back into the vial.
-  **12** Detach the syringe with plunger rod from the vial adapter by turning counter-clockwise. Attach the syringe to the infusion set provided and inject the reconstituted product intravenously (K). **Note:** follow instructions for infusion set provided.

Rate of Administration

The entire dose of Jivi® can usually be infused within 1 to 15 minutes. The maximum rate is 2.5 mL per minute. Your healthcare provider will determine the rate of administration that is best for you.

INDICATIONS

- Jivi is an injectable medicine used to replace clotting factor (Factor VIII or antihemophilic factor) that is missing in people with hemophilia A.
- Jivi is used to treat and control bleeding in previously treated adults and adolescents (12 years of age and older) with hemophilia A. Your healthcare provider may also give you Jivi when you have surgery. Jivi can reduce the number of bleeding episodes in adults and adolescents with hemophilia A when used regularly (prophylaxis).
- Jivi is not for use in children below 12 years of age or in previously untreated patients.
- Jivi is not used to treat von Willebrand disease.

IMPORTANT SAFETY INFORMATION

- You should not use Jivi if you are allergic to rodents (like mice and hamsters) or to any ingredients in Jivi.
- Tell your healthcare provider about all of your medical conditions that you have or had.
- Tell your healthcare provider if you have been told that you have inhibitors to Factor VIII.
- Allergic reactions may occur with Jivi. Call your healthcare provider right away and stop treatment if you get tightness of the chest or throat, dizziness, decrease in blood pressure, or nausea.
- Allergic reactions to polyethylene glycol (PEG), a component of Jivi, are possible.
- Your body can also make antibodies, called "inhibitors," against Jivi, which may stop Jivi from working properly. Consult your healthcare provider to make sure you are carefully monitored with blood tests for the development of inhibitors to Factor VIII.
- If your bleeding is not being controlled with your usual dose of Jivi, consult your doctor immediately. You may have developed Factor VIII inhibitors or antibodies to PEG and your doctor may carry out tests to confirm this.
- The common side effects of Jivi are headache, cough, nausea, and fever.
- These are not all the possible side effects with Jivi. Tell your healthcare provider about any side effect that bothers you or that does not go away.

For additional important risk and use information, please see the [full Prescribing Information](#).

You are encouraged to report side effects or quality complaints of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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antihemophilic factor
(recombinant) PEGylated-acl