

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 KOVALTRY®. If a package is opened or damaged, do not use this component. If these components cannot be used, please contact your healthcare provider.

Prepare a clean flat surface and gather all the materials needed for the infusion.

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 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).

11 Withdraw all the solution 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 administration set provided and inject intravenously (K). NOTE: follow instructions for infusion set provided.

Rate of administration

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

INDICATIONS

- ▶ KOVALTRY® is a medicine used to replace clotting factor (Factor VIII or antihemophilic factor) that is missing in people with hemophilia A.
- ▶ KOVALTRY® is used to treat and control bleeding in adults and children with hemophilia A. KOVALTRY® can reduce the number of bleeding episodes in adults and children with hemophilia A when used regularly (prophylaxis). Your healthcare provider may give you KOVALTRY® when you have surgery.
- ▶ KOVALTRY® is not used to treat von Willebrand Disease.

IMPORTANT SAFETY INFORMATION

- ▶ You should not use KOVALTRY® if you are allergic to rodents (like mice and hamsters) or any ingredients in KOVALTRY®.
- ▶ Tell your healthcare provider if you have heart disease or are at risk for heart disease.
- ▶ The common side effects of KOVALTRY® are headache, fever, and itchy rash.
- ▶ Allergic reactions may occur with KOVALTRY®. Call your healthcare provider right away and stop treatment if you get tightness of the chest or throat, dizziness, decrease in blood pressure, and nausea.
- ▶ Your body can also make antibodies, called "inhibitors," against KOVALTRY®, which may stop KOVALTRY® 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.
- ▶ Tell your healthcare provider about any side effect that bothers you or that does not go away.
- ▶ Call your healthcare provider right away if bleeding is not controlled after using KOVALTRY®.

For additional 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.

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Kovaltry®

Antihemophilic Factor (Recombinant)