

Xyntha® Single Use Vial Reconstitution

***** IMPORTANT *****

Aseptic techniques must be used at all times.

Supplies Required:

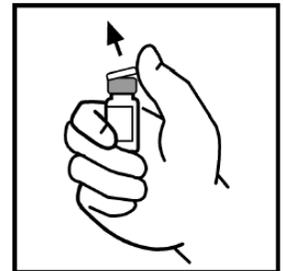
- Use only the materials and pre-filled syringe of diluent (0.9% sodium chloride) provided in the Xyntha kit for reconstituting the product.
- Luer Lock syringe (large enough to contain dose) if:
 - You are combining multiple vials*
 - The pre-filled glass syringe with diluent is not compatible with the needless connector for the patient's intravenous catheter**

Instructions:

*Note: If you are reconstituting multiple vials of Xyntha, each vial should be individually dissolved according to the instructions below. Step 12 provides instructions for combining multiple vials once they have been reconstituted, using a separate larger luer lock syringe to draw back the dissolved content of each vial. Do not detach the diluent syringes or the large luer lock syringe until you are ready to attach the large luer lock syringe to the next vial adapter.

**Note: The pre-filled glass syringe with diluent used to reconstitute and administer product may not be compatible with all needless connectors for intravenous catheters (e.g. ICU Medical MicroClave® Neutral Connector). You may need to withdraw reconstituted product into a sterile 10 mL plastic syringe with a standard luer-lock connector.

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



3. Wipe the top of the vial with the alcohol swab provided, or use another antiseptic solution, 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 cover from the clear plastic vial adapter package. Do not remove the adapter from the package.

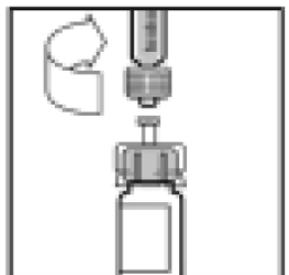
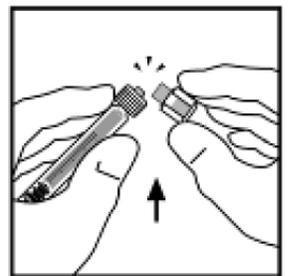
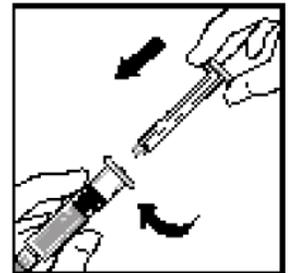
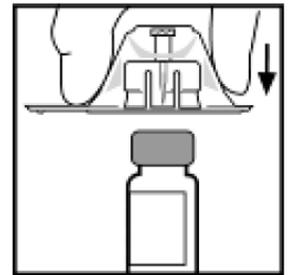
5. Place the vial on a flat surface. While holding the adapter in the package, place the vial adapter over the vial. Press down firmly on the package until the adapter snaps into place on top of the vial, with the adapter spike penetrating the vial stopper.

6. Grasp the plunger rod as shown in the diagram. Avoid contact with the shaft of the plunger rod. Attach the threaded end of the plunger rod to the diluent syringe by pushing and turning firmly.

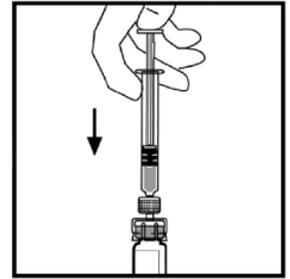
7. Break off the tamper-resistant plastic-tip cap from the diluent syringe by snapping the perforation of the cap. This is done by bending the cap up and down until the perforation is broken. Place the cap on its top on a clean surface. Do not touch the inside of the cap or the syringe tip.

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

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 Xyntha vial



- 11 With the syringe still connected to the adapter, gently swirl the contents of the vial until the powder is dissolved.

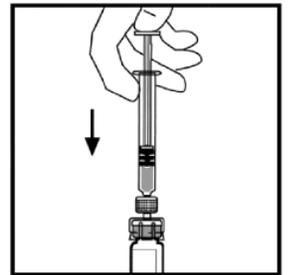
The final solution should be clear to slightly pearly and colourless, with no particulate matter. If it is not, the solution should be discarded and a new kit should be used.

- 12 For a single vial:

- Ensuring that the syringe plunger rod is still fully depressed, invert the vial. Slowly draw the solution into the syringe*.

For multiple vials:

- Remove the diluent syringe from the vial adapter, leaving the vial adapter attached to the vial.
- Quickly attach a separate larger luer lock syringe and draw back the dissolved contents as instructed above.
- Repeat this procedure with each vial in turn. Do not detach the diluent syringes or the large luer lock syringe until you are ready to attach the large luer lock syringe to the next vial adapter.



- 13 Detach the syringe from the vial adapter by gently pulling and turning the syringe counterclockwise. Discard the vial with the adapter attached.

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

COMMENTS:

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References: Xyntha® (moroctocog alfa) Product Monograph www.pfizer.ca

For questions or comments about this document, please contact Transfusion.SafetyTeam@ahs