

Rev 1.01

Leaders in Laboratory Medicine

Applicability

This document applies to all APL, AHS, Covenant Health, and other health care professionals involved in the transfusion of blood components and products in Alberta.

Supplies Required

Use only the supplies and pre-filled syringe of diluent provided with the product for reconstituting the product.

Contained in Box

- Vial of lyophilized product
- 1 mL sterile water for injection in a pre-filled syringe
- Vial adapter with filter

Separate Supplies

- Sterile plastic 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 connect for the patient's intravenous catheter**
- IV administration pump and set (if required)
- Alcohol swabs



Aseptic technique must be used at all times

Instructions:

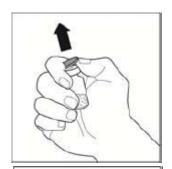
*Note: If you are reconstituting multiple vials, each vial should be individually dissolved according to the instructions below, then use a separate larger luer lock syringe to draw back the dissolved content of each vial.

**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.

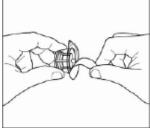


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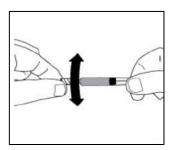
- 1. Bring the product to room temperature
- 2. Remove the cap from the OBIZUR vial to expose the central portion of the rubber stopper and place on a clean surface. Cleanse the rubber stopper with an alcohol swab (not supplied) and allow it to dry prior to use.



3. Peel back the cover of the vial adapter package. Be careful not to touch the luer lock (tip) in the center of the vial adapter. Leave the vial adapter in the package and place it on a clean surface with the luer lock pointing up.



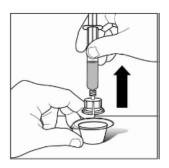
4. Snap off the tamper resistant cap of the pre-filled syringe and place it on a clean surface.



5. Firmly hold the package containing the vial adapter on a clean, flat surface. Connect the pre-filled syringe to the vial adapter by pushing the syringe tip down onto the luer lock in the center of the vial adapter, and screw until the syringe is secured.



6. Carefully lift up the combined syringe and vial adapter and remove it from the plastic package.



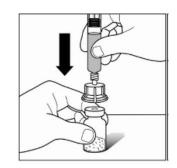


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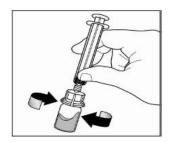
7. With one hand, continue to hold the combined syringe and vial adapter. With the other hand, hold the OBIZUR vial tightly on a clean, flat surface.

In a continuous motion, place the vial adapter over the OBIZUR vial. Firmly push the filter spike of the vial adapter through the center of the OBIZUR vial's rubber circle until the clear plastic cap snaps onto the vial.

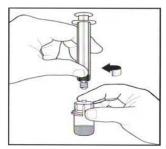
Some of the liquid in the pre-filled syringe may automatically transfer into the OBIZUR vial. Push the plunger down to complete the transfer of all liquid from the syringe into the OBIZUR vial.



8. With the syringe and the vial still attached, gently swirl (in a circular motion) until the product is fully dissolved / reconstituted.



9. With one hand hold the vial and vial adapter, and with the other hand firmly grasp the barrel of the pre-filled syringe and unscrew the syringe from the vial adapter.



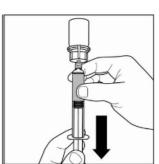
10. Once all vials have been reconstituted, using a new large sterile syringe of the appropriate size for the volume (not supplied), pull back the plunger and admit air into the syringe.

Connect the large syringe to the vial adapter by pushing the syringe tip down onto the luer lock in the center of the vial adapter, and screw until the syringe is secured.



Unscrew the large syringe and repeat this process for all reconstituted vials of OBIZUR, until total volume to be administered is reached.

11. Label the syringe with a medication label per AHS Labelling Medications Guideline





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Contact Information

For questions or comments about this document, please contact <u>Transfusion.SafetyTeam@aplabs.ca</u>

References

Obizur® Product Monograph. Available from www.takeda.com Labelling Medications AHS Guideline HCS-185-01