Xyntha/Xyntha Solofuse

TRANSFUSION MEDICINE SERVICES

CLASSIFICATION	ALERTS
Recombinant Coagulation Factor VIII Product	None

PREPARATION and ADMINISTRATION

Xyntha is a recombinant factor VIII product and does not contain human plasma therefore a blood consent is not required.

Reconstitution

Diluent: sterile water for injection

See pages 3-5 for Xyntha and 5-8 for Xyntha Solofuse reconstitution steps -administer within 3 hours of reconstitution

After reconstitution, inspect visually for particulate matter prior to administration.

IV Direct	Intermittent Infusion	Continuous Infusion
IV Direct is the recommended route of administration. Professionals performing these restricted activities must have received authorization from their regulatory College and have the knowledge and skill to perform the skill competently Administer dose as reconstituted solution over several minutes. The patient's comfort level should determine the rate of infusion. If no indwelling IV, use the butterfly and supplies provided in the box.	**IV Bag (large volume pump)**	**IV Bag (large volume pump)**
	Not Recommended	Not applicable
	Syringe (syringe pump)	**Syringe (syringe pump)**
	Not Recommended	Not applicable

Requirements and Monitoring

Baseline vitals before starting infusion. Reassess 15 min after infusion.

Document all vitals taken.

Blood pressure via cuff or arterial line
Temperature
Heart Rate
Respirations

Keep unopened back up bag of NS and standard IV tubing nearby for prompt response if an adverse event (AE) occurs.

INDICATIONS

Xyntha, Antihemophilic Factor (Recombinant) [BDDrFVIII] is indicated for:

- The control and prevention of hemorrhagic episodes
- Routine and surgical prophylaxis in patients with hemophilia A (congenital factor VIII deficiency or classic hemophilia).

ADVERSE EFFECTS

The most frequently reported adverse reaction, on a per infusion basis, was vomiting. Most adverse reactions reported were considered mild or moderate in severity. In addition, as with any intravenous protein product, allergic type hypersensitivity reactions are possible. Manifestations of hypersensitivity reactions may include hives, generalized urticaria, tightness of the chest, wheezing, hypotension, and anaphylaxis.

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If an AE is suspected: stop the infusion, and consult the authorized prescriber (AP) for medical management. Notify the TM lab of a suspected reaction.

- Review the product lot number, TM tag and patient ID to rule out a verification (clerical) error and that the expiry date and time has not passed.
- Resume infusion cautiously as directed by AP. Directly observe patient x5min then closely observe x10min.
- Ensure TM tag, along with a copy of the documented clinical data and interventions are sent to TM lab once infusion is discontinued or completed.

DOSAGE

Consult the Bleeding Disorders Clinic or the Hematologist on call for appropriate dosing prior to initial dose:

Ask patient if they have a Factor First card supplying the recommended treatment and dosage

(Adult) Hereditary Bleeding Disorder Clinic 902-473-5612. After hours call 902-473-2220.
(Pediatric) IWK Bleeding Disorder Clinic 902-470-8752. After hours call 1-888-470-8888.

For patient specific dosing at the IWK please see Complex Care Management Plan in the "Alerts" section under "Scanned Permanent Health Records" in the IWK MEDITECH MAGIC system

COMPATIBILITY, STABILITY

- Compatible with NS
- Single use vials. Do not use past expiry date
- Do not dilute in any IV solutions
- Prior to reconstitution, vials should be stored in their supplied box to protect from light
- Do not store unused vials in refrigerator. Administer at room temperature

DOSAGE FORMS

- Supplied by Transfusion Medicine (Blood Bank)

MISCELLANEOUS

- None

RECONSTITUTION

Xyntha Vial Kit:

1. Allow the vial of freeze-dried Xyntha powder and the pre-filled diluent syringe to reach room temperature. Don clean gloves.

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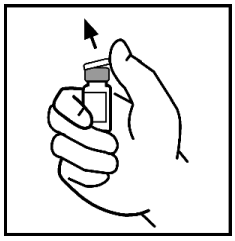
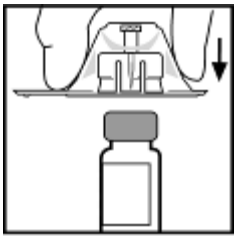
2. Remove the plastic flip-top cap from the Xyntha vial to expose the central portions of the rubber stopper.



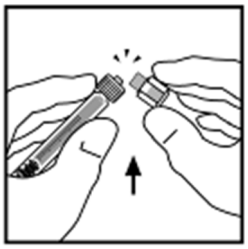
3. Wipe the top of the vial with the alcohol swab provided, or use another antiseptic solution, and allow to dry. After cleaning, do not touch the rubber stopper with your hand or allow it to touch any surface

4. Peel back the cover from the clear plastic vial adapter package. **Do not remove the adapter from the package**.

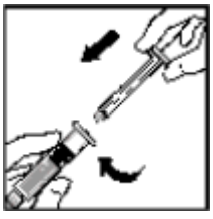
5. Place the vial on a flat surface. While holding the adapter in the package, place the vial adapter over the vial. Press down firmly on the package until the adapter snaps into place on top of the vial, with the adapter spike penetrating the vial stopper.



6. 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. Do not touch the inside of the cap or the syringe tip. The diluent syringe may need to be recapped (if the dissolved Xyntha is not used immediately), so place the cap on its top on a clean surface in a spot where it would be least likely to become contaminated.



7. 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.



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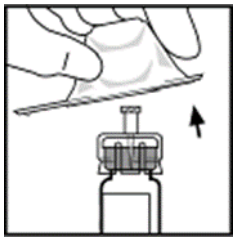
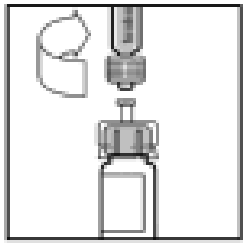
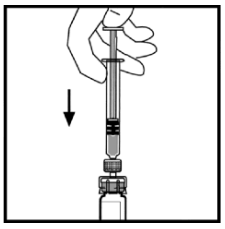
8. Lift the package away from the adapter and discard the package.



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

Note: If you prepared more than one vial of Xyntha, remove the diluent syringe from the vial adapter, leaving the vial adapter attached to the vial. Quickly attach a separate large 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.

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

Note: The final solution should be inspected visually for particulate matter before administration. The solution should be clear to slightly pearly and colorless. If it is not, the solution should be discarded and a new kit should be used.

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

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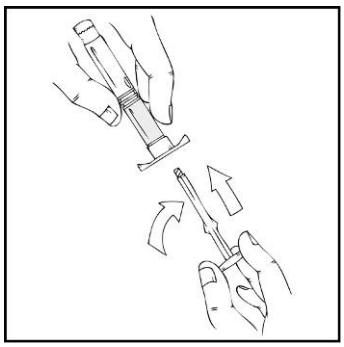
Xyntha Solofuse:

1. Allow the prefilled dual-chamber syringe of freeze-dried Xyntha to reach room temperature. Don clean gloves.

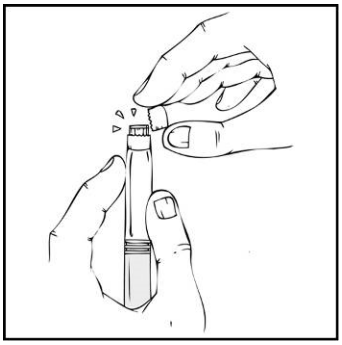
2. Remove the contents of the Xyntha Solofuse Kit and place on a clean surface, making sure you have all the supplies you will need.

3. Grasp the plunger rod as shown in the following diagram. Avoid contact with the shaft of the plunger rod. Screw the plunger rod firmly into the opening in the finger rest of the Xyntha Solofuse by pushing and turning firmly until resistance is felt (approximately 2 turns).



Note: Once the white tamper-evident seal is removed it is important to keep the Xyntha Solofuse in the upright position throughout the reconstitution process to prevent possible leakage.

4. Holding the Xyntha Solofuse upright, remove the white tamper-evident seal by bending the seal right to left (or a gentle rocking motion) to break the perforation of the cap and expose the grey rubber tip cap of the Xyntha Solofuse.



5. Remove the protective blue vented sterile cap from its package.

While holding the Xyntha Solofuse upright, remove the grey rubber tip cap and replace it with the protective blue vented cap (prevents pressure build-up). Avoid touching the open end of both the syringe and the protective blue vented cap.

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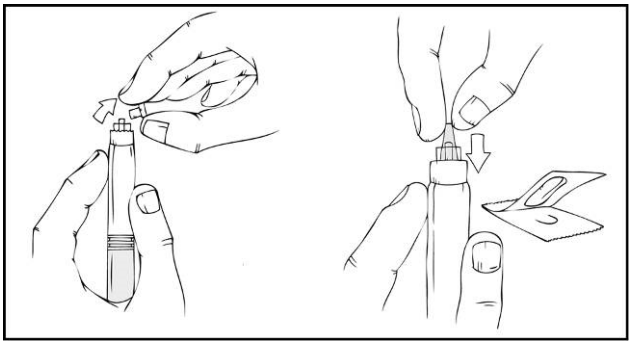
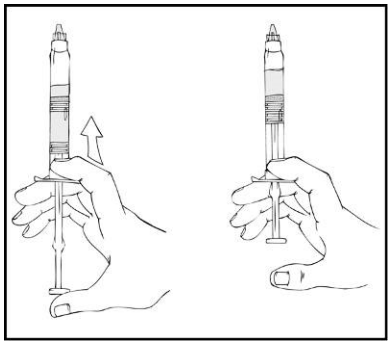
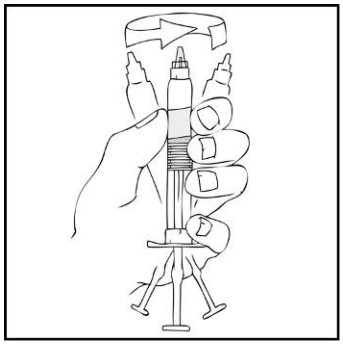


6. **Gently and slowly** advance the plunger rod by pushing until the two stoppers inside the Xyntha Solofuse meet, and all of the diluent is transferred to the chamber containing the Xyntha powder.

Note: To prevent the escape of fluid from the tip of the syringe, the plunger rod should not be pushed with excessive force.



7. With the Xyntha Solofuse remaining upright, swirl **gently** several times until the powder is dissolved.



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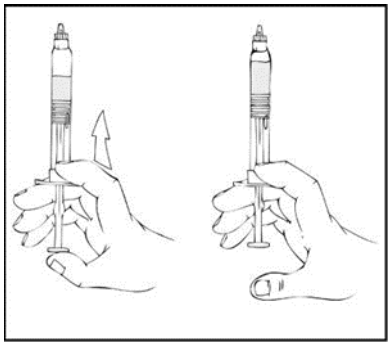
8. Again, holding the Xyntha Solofuse in an upright position, slowly advance the plunger rod until most, but not all, of the air is removed from the drug product chamber.



REFERENCES

- CL-BP-030, IWK-625 Blood Component and Blood Product Administration – Policy and Procedure
- Xyntha product monograph. Found at https://www.pfizer.ca/en/our-products