Alberta Health Services

This document applies to all Covenant and AHS sites.

Xyntha®

Class: *Manufactured Anti-hemophilic recombinant product*

OTHER NAMES: moroctocog alpha, anti-hemophilic factor (B-domain deleted recombinant), antihemorrhagic blood coagulation factor VIII

Company: Pfizer Canada Inc.

	INTRAVENOUS			OTHER		
ROUTES	**DIRECT IV**	**IV Infusion**	**Continuous Infusion**	**SC**	**IM**	**OTHER**
Acceptable Routes*	Yes**	Yes	No	No	No	N/A

*** Professionals performing these restricted activities have received authorization from their regulatory college and have the knowledge and skill to perform the skill competently.**

**** Transfusion of Blood Components and Products Learning Module Section Three: Direct IV Administration of Blood Products. RNs may administer direct IV blood products. Not to be confused with medication administration**

DESCRIPTION OF PRODUCT:

- Xyntha® is a sterile, lyophilized, purified, and viral-inactivated concentrate of recombinant Factor VIII.
- Two formats are available:
  - Xyntha®: a lyophilized powder for reconstitution in a single use vial. Available in 250 IU and 500 IU sizes
  - Xyntha® Solofuse™: a lyophilized powder for reconstitution in a prefilled dual-chamber syringe. Available in 500 IU, 1000 IU, 2000 IU and 3000 IU sizes
- Diluent is 0.9% Sodium Chloride.
- Also contains Polysorbate 80, sucrose, L-histidine, and calcium chloride dehydrate
- **Note:** Xyntha® and Xyntha® Solofuse™, with the exception of packaging and reconstitution, are considered the same product for the remainder of this document and referred to as Xyntha®

AVAILABILITY:

- Supplied by CBS
- Contact your local laboratory/transfusion service regarding stock availability on site.

INDICATIONS FOR USE:

- Control and prevention of hemorrhagic episodes in patients with hemophilia A.
- Routine and surgical prophylaxis in patients with hemophilia A.

CONTRAINDICATIONS:

- Patients with von Willebrand Disease (Xyntha® does not contain von Willebrand Factor).
- May be contraindicated in patients with known hypersensitivity to mouse or hamster protein.
- Known hypersensitivity to any of the constituents in the formulation of Xyntha®

WARNINGS:

- Development of activity-neutralizing antibodies has been detected in patients receiving factor VIII-containing products. If expected plasma factor VIII activity levels are not attained, or if bleeding is not controlled with an appropriate dose, an assay that measures factor VIII inhibitor concentration should be performed.
- Anaphylaxis and anaphylactoid reactions are possible.

DOSE (Refer to Product Insert):

- Dosage must be individualized to the severity of factor VIII deficiency, location and extent of bleeding, presence of inhibitors, Factor VIII level desired, and the patient's clinical condition.
  Consult with hematologist or the bleeding disorder clinic.
- The required dosage is calculated using the following formula:

  Required Units=body weight (kg) x desired factor VIII rise (IU/dl or % of normal) x 0.5 (IU/kg per IU/dl)

  This calculation is based on empirical data that demonstrates, on average, 1 IU of factor VIII per kg body weight raises the plasma factor VIII activity by 2 IU/dl.

ADMINISTRATION:

Confirm written (signed) consent has been obtained and documented prior to requesting blood component from lab/transfusion service where possible.

Pre-Infusion: Ensure recent patient weight is on file and pertinent labs are available. Perform the appropriate pre-transfusion checks per protocol.

Access: Xyntha® can be given via CVC, PICC, Port-a-Cath®, or peripheral IV line.

Reconstitution Supplies:

- Xyntha®, lyophilized in single dose vial (Xyntha®) or in a prefilled dual chamber syringe (Xyntha® Solofuse™)
- Diluent (0.9% Sodium Chloride) in a prefilled syringe (Xyntha®) or dual chamber syringe (Xyntha® Solofuse™)
- One plunger rod for assembly
- 1 vented sterile cap

Contained in box

- **If more than one vial per dose is required:**
  - Sterile plastic Luer lock syringe large enough to contain dose if more than vial per dose is required (not provided in kit)
  - Luer-to-luer syringe connector (for Xyntha® Solofuse™) (not provided in kit)

Administration Supplies:

NOTE: Included glass syringe maybe incompatible with ICU Medical MicroClave® Neutral Connector. Draw up reconstituted product with a sterile plastic luer-lock syringe for administration as required.

- **For direct IV administration:**
  - Sterile infusion set (provided in kit), if no established IV access
- **For IV infusion:**
  - Syringe pump (preferred) or IV pump
  - Syringe pump tubing, or appropriate IV administration set (buretrol preferred)

Do not administer in the same tubing or mix with other medicinal products.

Reconstitution:

For Xyntha® Solofuse™ reconstitution, refer to:
http://www.albertahealthservices.ca/assets/wf/lab/wf-lab-clin-tm-xyntha-solo-reconst-inst.pdf

For Xyntha® single use vial reconstitution refer to:
http://www.albertahealthservices.ca/assets/wf/lab/wf-lab-clin-xyntha-reconst-inst.pdf

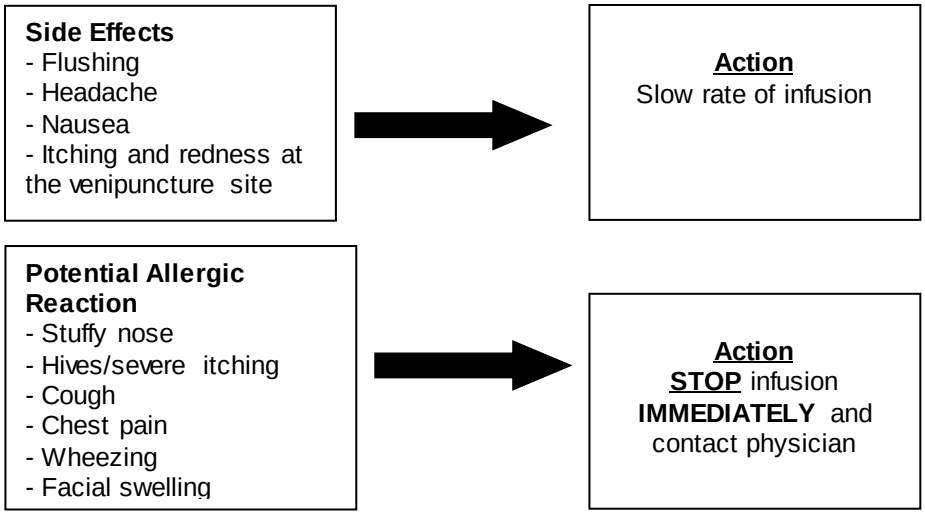
For combined Xyntha® single use vial and Xyntha® Solofuse™ reconstitution refer to:
http://www.albertahealthservices.ca/assets/wf/lab/wf-lab-clin-xyntha-comb-reconst-inst.pdf

Administration:

- Give within a maximum of 3 hrs of reconstitution.
- **Administration rate:** Administration rate should be determined by the ordering physician, local bleeding disorders clinic, and as tolerated by the patient.

POTENTIAL HAZARDS WITH PARENTERAL ADMINISTRATION:

- Potential adverse events related to a blood product transfusion range in severity from minor with no sequelae to life-threatening.
- All adverse events occurring during a transfusion should be evaluated to determine whether or not the transfusion can be safely continued/restarted.
- All adverse events suspected to be related to a product transfusion (whether during or after a transfusion) should be reported to your local transfusion service.



NURSING IMPLICATIONS:

Patient Monitoring:

- Vital Signs: Pre-administration**,** on completion of dose, and as patient condition requires (see administration rate).

Patients receiving blood product transfusions must be observed closely for signs of any unexpected or untoward reactions. These reactions may occur during or after the infusion of blood or blood products. For follow up instructions to a transfusion reaction, see http://www.albertahealthservices.ca/4240.asp

Documentation:

- The transfusion documentation should be double signed (where required) to indicate infusion. Document start and stop date and time of transfusion.
- Assessment of patient tolerability should be documented in appropriate flow chart or clinical record (electronic or paper) as required.

STORAGE & STABILITY OF PRODUCT:

- Stored at 2-8°C. **Do not freeze.**
- May be stored for up to 3 months at room temperature (< 25 ºC) Do not exceed expiry date. Can be returned to refrigerated storage after 3 months until expiry. Do not return to room temperature storage again.
- Expiration date is indicated on bottle
- Administer within 3 hours of reconstitution (reconstituted product can be stored at room temperature until administered)

COMMENTS:

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

LINK to WEBSITE for PRESCRIBING INFORMATION:

http://www.pfizer.ca