ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

Xyntha®

APPLICABILITY: This document applies to all APL, AHS, Covenant Health, and all other health care professionals involved in the transfusion of blood components and products in Alberta.	***Other Names:*** *moroctocog alpha, anti-hemophilic factor (B-domain deleted recombinant), antihemorrhagic blood coagulation factor VIII* ***Company:*** *Pfizer Canada Inc.* ***Class:*** *Manufactured Anti-hemophilic recombinant product*

In the event of discrepancy between APL Monograph and Manufacturer's documentation or patient resources, the APL Monograph will take precedence.

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

* Administration of blood components and blood products is a restricted activity. For specific conditions that apply to a profession's authorization to administer blood components and blood products, consult the applicable discipline-specific regulation under the Health Professions Act (Alberta). Health care professionals with this authorization require the applicable education, training and competency.

** Direct IV administration of blood products may be performed by health care professionals that have authorization of administration of blood products within their scope of practice.

DESCRIPTION:

- 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 500 IU size.
  - 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 dihydrate.
- **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 Canadian Blood Services.
- 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 hamster protein.
- May be contraindicated in patients with 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:

- 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.

- **Bleeding and Surgery dosing recommendations:**

Bleeding or Surgery Type	FVIII Level Required (% or IU/dL)	Frequency and Duration
Minor e.g. early hemarthrosis - superficial muscle, soft tissue - oral	20 – 40	**- Frequency:** every 12 – 24 hours as needed. **- Duration:** minimum 1 day, or until resolved (depends on severity).
Moderate e.g. bleeding into muscle - mild head trauma - oral cavity bleed - minor surgeries (e.g. tooth extraction)	30 – 60	**- Frequency:** every 12 – 24 hours as needed. **- Duration:** 3 – 4 days, or until adequate hemostasis achieved . - For tooth extraction: single infusion and oral antifibrinolytic therapy within 1h may be adequate.
Major e.g. GI bleed, intra-abdominal bleed - intracranial bleed - intrathoracic bleed - fractures - major surgeries	60 – 100	**- Frequency:** every 8 – 12 hours. **- Duration:** • Bleeds: until resolved. • Surgeries: until adequate hemostasis achieved plus at least an additional 7 days.

ADMINISTRATION:

Confirm signed consent has been obtained and documented prior to requesting blood components or products (human-source) 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, 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 (Xyntha Solufuse™)

} Contained in box

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

Administration Supplies:

NOTE: Included glass syringe may be incompatible with needless connectors on IV lines (e.g. 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

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

Reconstitution:

For Xyntha® Solofuse™ reconstitution, refer to:
Xyntha Solofuse Reconstitution Instructions

For Xyntha® single use vial reconstitution refer to:
Pre-Filled Syringe with Vial Adapter Reconstitution Instructions

For combined Xyntha® single use vial and Xyntha® Solofuse™ reconstitution refer to:
Combined Use of Xyntha Single-use Vial and Xyntha Solufuse Kit Reconsitution Instructions

Compatible IV Solutions:

- 0.9% sodium chloride (i.e. normal saline) may be used to flush as needed.

Administration:

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

NURSING IMPLICATIONS:

Patient Monitoring:

- Vital Signs: Pre-administration, on completion of dose, and as patient condition requires.
- If the patient has experienced previous adverse reaction to product transfusion, or this is the first transfusion of product for patient, monitor for 30-60 minutes post.

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 to a transfusion reaction see Transfusion Reactions | Alberta Health Services. Notify the transfusion service as soon as possible that an adverse reaction has occurred.

Documentation:

- Ensure documentation is completed as per the AHS Transfusion of Blood Components and Products Policy.
- Start and stop time of infusion and assessment of patient tolerability should be documented in appropriate flow chart or clinical record (electronic or paper).
- Document vital signs as required in the appropriate flow chart or clinical record (electronic or paper).
- Provide patient notification of transfusion documentation where required.

POTENTIAL HAZARDS WITH PARENTERAL ADMINISTRATION:

Adverse Events

- 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) must be reported to your local transfusion service.
- The most common adverse reactions observed are joint inflammation, hematoma, arthralgia, hypersensitivity, rash, pruritis, erythema, headache, pyrexia, elevated thrombin-antithrombin levels and increased blood lactate dehydrogenase.
- The most serious adverse reactions observed are hypersensitivity, acute ischemia.

Side Effects - Flushing - Headache - Nausea - Itching and redness at the venipuncture site	→	**Action** Slow rate of infusion
Potential Allergic Reaction - Stuffy nose - Hives/severe itching - Cough - Chest pain - Wheezing - Facial swelling - Fainting	→	**Action** **STOP** infusion **IMMEDIATELY** and contact physician

STORAGE & STABILITY:

- 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 one time only to refrigerated storage after 3 months until expiry.
- Expiration date is indicated on bottle.
- Administer within 3 hours of reconstitution (reconstituted product can be stored at room temperature until administered).

CONTACT INFORMATION:

Approved By: APL Transfusion Medicine Discipline Council
For questions or comments regarding this document please contact: Transfusion.SafetyTeam@aplabs.ca

REFERENCES:

NiaStase® Product Monograph. Available from http://www.pfizer.ca.