



TM40-01.02.155 Nuwiq® Antihemophilic Factor

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: <i>Recombinant Factor VIII, anti-hemophilic factor (recombinant B-Domain Deleted), simotocog alfa</i> Company: <i>Octapharma Canada Inc.</i> Class: <i>Manufactured anti-hemophilic recombinant factor</i>		
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: - Nuwiq® is a sterile, non-pyrogenic, preservative-free, lyophilized, white to off-white powdered concentrate of recombinant human coagulation factor VIII for intravenous administration. - Available in dose sizes of 250, 500, 1000, 2000, 3000 and 4000 IU with 2.5 mL of solvent - No human or animal derived additives are added during the manufacturing process - Produced by recombinant DNA technology in human cells, then purified by chromatography steps and solvent/detergent treatment for virus inactivation/removal - The diluent is Sterile Water for Injection, and is supplied in a pre-filled syringe.						
AVAILABILITY - Supplied by Canadian Blood Services. - Contact your local laboratory/transfusion service regarding stock availability on site.						
INDICATIONS FOR USE: Indicated in adults and children with hemophilia A (congenital factor VIII deficiency) for: - Routine prophylactic treatment to prevent or reduce the frequency of bleeding episodes - Control and prevention of bleeding episodes (e.g. in trauma or procedures with increased risk of bleeding). - Perioperative management (surgical prophylaxis)						
CONTRAINDICATIONS: - Known hypersensitivity to the product or any of the constituents in the formulation of Nuwiq® (contains sucrose, sodium chloride, arginine hydrochloride, sodium citrate and poloxamer 188) - Does not contain vWF and should not be used to treat von Willebrand disease						
MANUFACTURER’S 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:

1 IU of Nuwiq® per kg body weight is expected to increase, on average, the circulating level of factor VIII by 2% of normal activity.

- 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.
- More frequent or higher doses may be required in the presence of low titre inhibitors (See product insert)
- Manufacturer's recommended dosage is calculated using the following formula:

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

Expected rise (% of normal) = 2 x administered IU/body weight (kg)

**** Consult with Hematologist or the bleeding disorder clinic.****



ADMINISTRATION:

Pre-Infusion:

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

Access:

- Nuwiq® can be given via CVC, PICC or peripheral IV line.

Reconstitution:

Contained in box:

- Nuwiq®, lyophilized in single dose vial
- Diluent (Sterile Water for Injection) in a prefilled syringe
- Vial adapter (contains filter)

Reconstitution: Refer to reconstitution steps with vial adapter at: [Prefilled Syringe with Vial Adapter Reconstitution Instructions](#)

Compatible IV Solutions:

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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
 - Sterile plastic luer-lock syringe (large enough to contain dose)
- **For IV infusion:**
 - Syringe pump (preferred) or IV pump
 - Syringe pump tubing, or appropriate IV administration set (ex. buretrol)

Administration:

- Give within a maximum of 3 hrs of reconstitution
- Dose issued may vary slightly from dose ordered based on vial sizing ($\pm 10\%$)
- **DO NOT** mix with other drugs or IV solutions

Administration rate: Recommended 4mL/min. Administration rate should be determined by the ordering physician, 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.

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 until indicated expiry date. **Do not freeze.**
- Protect from light.
- May be stored for a single period of up to 1 month at room temperature (up to 25 °C). **Cannot** be returned to refrigerated storage once removed.
- Expiration date is indicated on bottle and packaging. Do not exceed expiry date.
- Administer within 3 hours of reconstitution. Keep 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:

Nuwiq® product monograph:

https://pdf.hres.ca/dpd_pm/00068938.PDF