ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

wilate®
vWF and FVIII (human)

APPLICABILITY: This document applies to APL, AHS, Covenant Health, and all other health care professionals involved in the transfusion of blood components and products in Alberta.	***Other Names:*** Factor VIII and von Willebrand Factor (vWF) (human) ***Company:*** *Octapharma* ***Class:*** *Manufactured blood product, derived from human plasma*

	INTRAVENOUS			OTHER		
ROUTES	**DIRECT IV**	**IV Infusion**	**Continuous Infusion**	**SC**	**IM**	**OTHER**
Acceptable Routes*	Yes**	Yes	Yes	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.**

**** Direct IV Administration of Blood Products may be performed by professionals per the Transfusion of Blood Components and Products Learning Module. Not to be confused with medication administration.**

DESCRIPTION:

- Wilate® is a stable, lyophilized concentrate of human coagulation factor VIII (FVIII) and von Willebrand Factor (vWF) prepared from large pools of human plasma.
- Viral reduction/inactivation steps include solvent/detergent (S/D) inactivation and dry heat treatment.
- Reconstituted solution is clear or slightly opalescent, colourless or slightly yellow.
- Available in single-use vial sizes of 500 IU FVIII/500 IU vWF and 1000 IU FVIII/1000 IU) vWF.
- When reconstituted, solution contains 100 IU/mL FVIII and 100 IU/mL vWF.
- Also contains calcium chloride, glycine, sodium chloride, sodium citrate, sucrose, and Polysorbate 80.
- Latex-free.

AVAILABILITY:

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

INDICATIONS:

- Treatment and prophylaxis of spontaneous and trauma-induced bleeding episodes in patients with all types of von Willebrand Disease where DDAVP (desmopressin) is ineffective or contraindicated.
- Treatment and prophylaxis of patients with hemophilia A (congenital or acquired FVIII deficiency) and for the prevention and treatment of bleeding in minor surgical procedures.

CONTRAINDICATIONS:

- Patients with known anaphylactic or severe systemic reactions to human plasma-derived products or any ingredient in the formulation or components of the container.

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 expected dose, an assay that measures Factor VIII inhibitor concentration should be performed.
- Thromboembolic events may occur in VWD patients receiving VWF/FVIII replacement therapy, especially in patients at risk for thrombosis.

DOSE (Refer to Product Insert):

- Dose to be determined by the most responsible health practitioner (MRHP) only after consult with Hematologist or bleeding disorders clinic.
- Dosage and duration of treatment depend on the severity of the Factor VIII deficiency, location and extent of bleeding, presence of inhibitors, Factor VIII level desired, and the patient's clinical condition.
- After 24-48 hours of treatment, in order to avoid an excessive rise in FVIII:C, reduced doses and/or prolongation of the dose interval should be considered.

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 nursing protocol.

Access: Peripheral or central venous access site.

Reconstitution Supplies:

- wilate® product (lyophilized powder)
- Solvent (Sterile Water for Injection, included with product)
- Mix2Vial filter transfer set (included with product)
- Alcohol swabs
- Sterile plastic Luer lock syringe (large enough to hold prescribed dose)

Reconstitution:

- Bring wilate® to room temperature before reconstitution.
- See *Mix2Vial Reconstitution Instructions.*
- wilate® should be visually inspected for particulate matter and discoloration prior to administration. Do not use visibly cloudy solutions or solutions still containing flakes or particles after filtration.
- Do not dilute further.
- Do not refrigerate after reconstitution.

* Note: wilate can be administered through an administration set without a filter since filtering is achieved through reconstitution with the Mix2Vial device.

Compatible IV Solutions:

- wilate® must not be mixed with other medicinal products or solutions.
- Normal saline may be used to flush the line.

Administration Supplies:

- **Direct IV administration:**
  - Sterile plastic Luer lock syringe (large enough to contain dose)
- **IV infusion:**
  - IV administration set
  - IV pump

Administration:

- Give immediately after reconstitution.
- **Administration rate:**
  - Administration rate should be specified by the MRHP after patient assessment.
  - Recommended slow administration at a rate of 2-3 mL/min. (Pump rate: 120 mL/h – 180 mL/h).

NURSING IMPLICATIONS:

Patient Monitoring:

- Vital Signs: Pre-administration**,** on completion of dose, and as patient condition requires.
- Heart rate should also be monitored during infusion. Decrease rate or stop administration if a marked increase occurs.
- 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 instructions to a transfusion reaction, go to: www.albertahealthservices.ca/lab/page4240.aspx

Documentation:

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

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) must be reported to your local transfusion service.
- Rare cases of serious allergic/hypersensitivity reactions (which may include facial swelling, flushing, hives, blood pressure decrease, nausea, rash, restlessness, shortness of breath, tachycardia, tightness of the chest, tingling, urticaria and vomiting) have been reported, particularly in very young patients or patients who had who had previously reacted to other Factor VIII concentrates.

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:

- Store at 2-8°C until expiry.
- May be stored at room temperature (up to 25°C) for a single period of up to 6 months, or until the expiry date on the vial (whichever is shorter). Ensure the date the product is removed from the refrigerator is recorded. Once stored at room temperature, do not return the product to refrigerated storage.
- Protect from light.

CONTACT INFORMATION:

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

REFERENCES:

Octapharma Canada Inc. wilate® Product Monograph. May 2018. [Accessed 15Nov21]. https://www.octapharma.ca/api/download/x/1e0b8befe9/wilate-pm.pdf.

Transfusion of Blood Components and Blood Products. AHS Policy PS-59.