Alberta Health Services

This document applies to all Covenant and AHS sites.

wilate®

Class: *Factor VIII/von Willebrand Factor complex, human*

OTHER NAMES: Factor VIII (human) and von Willebrand Factor (vWF) (human)
Company: Octapharma

	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.**

**** 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:

- A stable, lyophilized concentrate of Antihemophilic factor (FVIII) and von Willebrand Factor (vWF) purified from pooled human plasma.
- Available in single-use vial sizes of: 500 units (IU) human Factor VIII/500 units (IU) human von Willebrand Factor (vWF) and 1000 units (IU) human Factor VIII/1000 units (IU) human von Willebrand Factor.
- When reconstituted, solution contains 100 IU/mL human FVIII and 100 IU/mL human vWF.
- Viral reduction steps include solvent/detergent (S/D) inactivation and dry heat treatment.
- **Latex-free**

AVAILABILITY:

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

INDICATIONS FOR USE:

- 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 life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components.

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.

DOSE:

- Treatment with wilate® should be done under the supervision of a physician with experience in coagulation disorders. Consult with Hematologist or local bleeding disorders clinic..
- **von Willebrand Disease:** Refer to product monograph supplied with product.
- **Hemophilia A:** Refer to product monograph supplied with product
  - 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.

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

Reconstitution Supplies:

- wilate®, lyophilized in single dose vial
- Solvent (Sterile Water for Injection) vial
- Mix2Vial™ filter transfer set

} Contained in box

- Alcohol swabs
- Sterile plastic Luer lock syringe (large enough to hold prescribed dose)

Administration Supplies:

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

Reconstitution: Refer to Mix2Vial™ instructions at: http://www.albertahealthservices.ca/assets/wf/lab/wf-lab-clin-tm-mix2vial-reconst-inst.pdf or in product insert.

Troubleshooting Mix2Vial™: Refer to instructions at: http://www.albertahealthservices.ca/assets/wf/lab/wf-lab-clin-tm-mix2vial-troubleshoot.pdf

Administration:

- Give immediately after reconstitution. **DO NOT** refrigerate after reconstitution.
- **Administration rate:** slowly at a rate of 2-3 mL/min. (Pump rate: 120 mL/h – 180 mL/h).
- Do **NOT** mix or administer with other medications.
- Do not dilute further.
- Normal saline can be used to flush IV administration set.

POTENTIAL HAZARDS WITH PARENTERAL ADMINISTRATION:

- 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.
- 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	→ **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

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.

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/lab/page4240.aspx

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 also 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**.
- Avoid extreme exposure to light.

COMMENTS:

Date Effective: 13 Sept 2019
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Approved By: APL Transfusion Medicine Discipline Council
Document Number: PTMGNR00024
Reference: wilate® Product Monograph
For questions or comments about this document, please contact Transfusion.SafetyTeam@ahs.ca

LINK to WEBSITE for PRESCRIBING INFORMATION:

Product monograph available at http://www.octapharma.com