Other Names	• Antihemophilic factor VIII and von Willbrand factor
Description	• Wilate is a plasma-derived, stable, highly purified concentrate of freeze-dried active human von Willebrand factor (VWF) and coagulation factor VIII (FVIII). • It is prepared from human donor plasma. • The determination of the VWF potency is carried out by determination of the Ristocetin Cofactor potency (VWF:Rco) by using the current "International standard for von Willebrand Factor Concentrate". • The potency of the FVIII is determined by using the current "International Standard for Human Coagulation Factor VIII Concentrate".

Special Approvals/Authorizations	• An independent 2 person check is required for all doses. Nurses from the Manitoba Bleeding Disorder Program are exempt from the independent 2 person check.
	• A nurse may administer a dose that provides:
	  ○ Up to 200 units greater than the prescribed dose; or
	  ○ No more than 100 units less than the prescribed dose without receiving a new medication order.
	• Patients accustomed to self-administering Factor VIII may continue to do so on the written order of a hematologist or designate.

Classification	**Special Populations:** **Geriatrics (greater than 65 years of age):** No information available. **Pregnant and nursing women:** Animal reproduction studies have not been conducted. Wilate should be used during pregnancy only if clearly indicated.
Indications	• Treatment and prevention of spontaneous and trauma-induced bleeding episodes in all types of VWD in adult and pediatric patients where use of DDAVP (1-Deamino-8-D-arginine vasopressin/desmopressin) treatment is ineffective or contra-indicated. • Treatment and prophylaxis of bleeding in patients with hemophilia A (congenital or acquired FVIII deficiency) and for the prevention and treatment of bleeding in minor surgical procedures.
Contraindications	• Contraindicated in individuals who are hypersensitive to this drug or to any ingredient in the formulation or component of the container. **WARNINGS:** • This product is prepared from large pools of human plasma, which may contain the causative agents of hepatitis and other viral diseases. The physician should discuss the risks and benefits of this product with the patient before prescribing or administering to the patient.
Supplied	Vial size is 500 international units and 1000 international units.
Dosage	**Note: Dosing in von Willebrand disease is calculated as RiCof units and in Hemophilia A is calculated as FVIII.** **Recommended dose and dose adjustment in von Willebrand disease:** **Patient response and lab monitoring guide dosing.** Mild/Moderate Hemorrhage: 20-40 *vWF/Riscof units/kg/dose* Major/Life-Threatening Hemorrhage: 40-50 *vWF/Riscof units/kg/dose* Minor Surgery: 30-60 *vWF/RisCof units/kg/dose* Prophylaxis: 20-30 *vWF/RisCof units/kg/dose* 1-3 times weekly

Recommended dose and dose adjustment in Hemophilia A:
Patient response and lab monitoring guide dosing. 1 unit/kg usually raises FVIII level by 1.5-2% of normal activity.

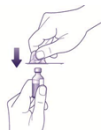
Mild/Moderate Hemorrhage:	10-20 units/kg
Major/Life Threatening Hemorrhage:	40-50 units/kg
Major Surgical Procedures:	20-50 units/kg
Prophylaxis:	20 units/kg at 2 to 3 day intervals

Reconstitution and Stability

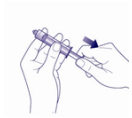
Reconstitution:

RECONSTITUTION INSTRUCTIONS

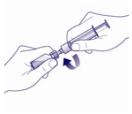
Bring the powder and solvent to room temperature (not above 25°C). Remove the plastic caps from the two vials. If the caps are loose or missing, do not use the vials. Clean the rubber stoppers on the vials with alcohol swabs and allow them to dry prior to use.



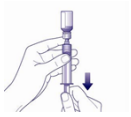
The product is reconstituted using the vial adapter included. Remove the protective paper from the vial adapter, without taking the vial adapter out of the protective cap. Attach the vial adapter to the solvent vial (sterile water). Take care not to touch the spike on the vial adapter. Once attached remove the protective cap from the vial adapter.



Pull the plunger to draw in a volume of air that is equal to the amount of solvent in the solvent vial (3.2 mL sterile water).



Screw the syringe tightly onto the vial adapter on the solvent vial. Inject air into the vial by pushing the plunger until you feel a clear resistance.



Hold the syringe with the solvent vial upside down. Pull the plunger to draw the solvent into the syringe.

Remove the empty solvent vial by tipping the syringe with the attached vial adapter.

Click the vial adapter, still attached to the syringe onto the powder vial. Hold the syringe slightly tilted with the vial facing downwards. Push the plunger slowly to inject the solvent into the powder vial. Make sure not to aim the stream of solvent directly at the powder as this will cause foaming.

Gently swirl the vial until all the powder is dissolved. Do not shake the vial as this will cause foaming. Check the solution for bits and discoloration. If you notice either, do not use it. The reconstituted product is a clear, colorless solution.
If you need a larger dose, repeat the procedure in a separate syringe until you have reached your required dose.

Ensure that the plunger is pushed all the way in before turning the syringe upside down (it may have been pushed out by the pressure in the syringe). Hold the syringe with the vial upside down and pull the plunger to draw up the amount calculated for the injection. Unscrew the vial adapter with the vial. The product is now ready for injection. Infuse according to instructions.

	Stability: • Stable at 2-8 ºC until the expiry date indicated on the label. • May be stored at room temperature up to 25 ºC for up to six months not to exceed the expiration date. • Once product is removed from the refrigerator, it cannot be returned to the refrigerator. • Do not freeze. • Protect from light. • Compatible to flush IV line with normal saline • Do NOT mix with other medicinal products.
Compatibilities/ Incompatibilities	• No other drugs / solutions (including normal saline) can be co-administered in the same line
Administration, Identification and ABO Compatibility	Refer to **Manitoba Best Practice Guidelines** • section 2.2 Standards- Identification and Administration • ABO Compatibility not applicable
Administration, Method	Maximum Concentration: • Not applicable Maximum Rate: • Administer at a rate of 4 mL per minute.
Adverse Events	• The most common adverse drug reactions were related to potential hypersensitivity reactions, including headache, pyrexia, pruritus, rash, and abdominal discomfort. • One subject was withdrawn from study due to an adverse drug reaction of rash. • There were no reports of any anaphylactic reactions or inhibitor formation in the clinical trials. **ADVERSE REACTIONS REPORTED:** CARDIOVASCULAR Thromboembolic events, hypotension, tachycardia GENERAL DISORDERS Lethargy Injection site burning and stinging NERVOUS SYSTEM DISORDERS Headache, restlessness GASTROINTESTINAL DISORDERS Nausea and vomiting IMMUNE SYSTEM DISORDERS Formation of neutralizing antibodies Fever and chills Hypersensitivity or allergic reactions (which may include angioedema, , flushing, hives, generalized urticaria, tightness of the chest, wheezing, hypotension and anaphylaxis
References:	Product Monograph – Date of Approval: January 12, 2012 Patient Medication Information
Reviewed By:	Dr. Donald Houston Dr. Jayson Stoffman