



wilate[®]

Human von Willebrand
factor (VWF)
and human Coagulation
Factor VIII (FVIII)

An Information Guide



octapharma

What is Wilate®?

- Wilate® is a high-purity plasma derived concentrate of both human von Willebrand Factor (VWF) and factor VIII (FVIII)
- Wilate® is for the treatment and prevention of bleeding episodes, and for the prevention and treatment of bleeding in minor surgical procedures in hereditary and acquired hemophilia A
- Wilate® is used to treat and prevent spontaneous and trauma-induced bleeds in all types of VWD in adult and pediatric patients where use of DDAVP treatment is ineffective or contra-indicated. Clinical data on controlling severe spontaneous bleeding are limited, and only minimal data exist to support the prophylactic use of wilate®. Wilate is also used for prevention and treatment of bleeding during and after surgical procedures.

How is Wilate® Made?

Viral safety has been a worldwide challenge in the past and major progress has been achieved in this area. In the particular case of wilate®, viral safety has been increased by having included two dedicated steps of viral inactivation/removal. Whilst *possibility of transmitting infective agents cannot be totally excluded* with products prepared from human plasma, wilate® manufacturing complies with the most rigid norms of viral safety.





Fresh-frozen plasma

Single units of plasma are combined (pooled) and, tested for HBV, HIV-1/2, HCV, and B19, before precipitation



S/D Treatment

Removal of enveloped viruses.



Chromatography and filtration

Additional steps for removal of potential viral contaminants.



Aseptic filling and Freeze-Drying

Wilate® is filled into vials and freeze-dried into powder form.



Perma-Heat Treatment

PermaHeat (100°C, 2h) inactivates both enveloped and non-enveloped viruses, but does not affect the VWF or FVIII.



Quality Control and Release

Scientific review ensures product standards have been met before entering the market.



What is von Willebrand Disease?

- WVD is an inherited bleeding disorder resulting from low levels or no VWF in the blood
- The blood does not clot naturally due to the lack or low level of VWF protein
- VWF helps platelets, which are small cell fragments in the blood, stick together to form blood clots that help stop bleeding when it happens
- Patients with VVD do not have enough VWF in their blood, or it does not work normally, so they can experience bleeding
- VWF also carries clotting FVIII, another protein that helps blood to clot

How Does Wilate® Help Patients with von Willebrand Disease?

- Wilate® is used to replace the VWF and FVIII proteins that are missing from the blood
- Wilate® increases the levels of VWF and FVIII to normal or near normal levels that can prevent or treat bleeds
- Wilate® is also used for VVD patients undergoing surgery to prevent and treat bleeding

What is Hemophilia A?

- Hemophilia is an inherited bleeding disorder in which a person's blood does not clot properly
- Hemophilia A is the result of a deficiency of FVIII protein, this protein is important to stop bleeding
- By replacement therapy with wilate[®], the plasma levels of FVIII are increased, thereby enabling a temporary correction of the factor deficiency and correction of the bleeding tendencies
- A complication of factor replacement therapy is the development of antibodies against the infused factor (known as inhibitors)
- In some patients, the immune system recognizes the infused factor as a foreign substance and stimulates the production of antibodies (inhibitors)

How Does Wilate[®] Help Patients with Hemophilia A?

- Wilate[®] increases the levels of FVIII and VWF – another protein that is also important to help blood clot – to levels that can prevent or treat bleeds

How are inhibitors managed?

- If an inhibitor develops, it reduces the clotting action of the factor product
- High doses of wilate[®] or other FVIII concentrate may be used to override the antibody to FVIII that the body has made
- Dose, frequency of infusion and duration of treatment or use of alternate treatment will be determined by your physician



How to Administer Wilate®?

- Wilate® is dissolved in a small injection volume (500 IU in 5 ml, 1000 IU in 10 ml)

Storage

- Wilate® and water can be stored at between +2°C and +8°C until the indicated expiry date. Within this period, wilate® and water may be stored for a single block of up to 6 months at room temperature (max. +25°C). If stored at room temperature (max. +25°C) wilate® must either be used within 6 months or discarded.
- Protect from light. Do not freeze. The reconstituted solution should be used on one occasion only. Any solution remaining should be discarded.

Packaging Information

Wilate® can be obtained in 2 sizes:

Wilate® 500 package contains:

- 1 vial with powder
- 1 vial with solvent (5 ml Water for Injections with 0.1% Polysorbate 80)
- Mix2Vial™ transfer set with integrated filter

Wilate® 1000 package contains:

- 1 vial with powder
- 1 vial with solvent (10 ml Water for Injections with 0.1% Polysorbate 80)
- Mix2Vial™ transfer set with integrated filter

Reconstitution Instructions

- Please read all steps thoroughly before proceeding
- Prepare at room temperature and on a stable surface



1. Wash hands, remove the bottle caps from the glass vials, then disinfect the rubber stoppers with alcohol swabs.



2. Remove Mix2Vial™ cover.



3. Firmly press blue end onto water vial.



4. Remove plastic packaging.



5. Holding the wilate® vial on a flat surface, place the water vial attached to the Mix2Vial™ directly over the rubber stopper and firmly press the transparent end onto the wilate® powder vial.



6. Still holding the water vial **MAINTAIN PRESSURE** until there is a complete transfer of water into the powder vial.





7. With both vials still attached, slowly swirl (to prevent formation of bubbles) the wilate® vial to ensure the product is fully dissolved to a clear solution.



8. After complete dilution, **UNSCREW THE TWO PARTS** of the Mix2Vial™ by holding the blue and transparent parts.



9. The transparent part must stay on the wilate® vial, as it contains the **FILTER** (15µ).



10. Attach (by screwing clockwise) a plastic sterile disposable syringe to the transparent part of Mix2Vial™.



11. Invert the system to a vertical position and draw the reconstituted wilate® into the syringe.

Wilate® is now ready for administration

Administration Instructions

- Inject the solution intravenously at a speed of 2-3 mL/minute immediately after reconstitution. DO NOT DILUTE AFTER RECONSTITUTION
- Discard the Mix2Vial™ (transparent plastic part) and the empty wilate® vial
- Record injected units in your diary

Are there any side effects I should know about?

Allergic reactions such as hives, itching, tightness of the chest, wheezing, chills, flushing, headache, feeling unusually tired, drowsy or restless, feeling sick or vomiting, and tingling of the skin, can occur with wilate®. If these symptoms occur contact your hemophilia doctor or nurse for advice before continuing treatment.

In rare cases, the allergic reactions are severe, known as shock or anaphylactic shock. The symptoms may include extreme difficulty breathing, or loss of consciousness. If this occurs, infusion should be stopped and emergency medical services contacted.

If the usual treatment for bleeding is not working, or if any unexpected effects occur while taking wilate®, contact your health professional as soon as possible.

For additional product information, please contact medinfo@octapharma.ca or call 1-888-438-0488.



Glossary

1. **acquired:** a non-hereditary type of bleeding disorder where a person suddenly develops an inhibitor (antibody)
2. **antibody:** a protein produced by the body's immune system when it detects foreign substances, called antigens
3. **contra-indicated:** against medical advice
4. **DDAVP (desmopressin):** a synthetic drug that acts by releasing VWF stored in the body
5. **double-inactivation:** two separate steps to kill or eliminate viruses
6. **hereditary:** transmission from one generation to another
7. **high-purity:** free from contaminants
8. **plasma derived:** a preparation of factor proteins manufactured from human plasma (blood)
9. **precipitation:** separating from solution or suspension
10. **viral inactivation:** process used to kill or eliminate viruses
11. **viral transmission:** passing a virus to another person
12. **HIV-1/2:** human immunodeficiency virus – 1 and 2
13. **HBV:** hepatitis B virus
14. **HCV:** hepatitis C virus
15. **B19:** human parvovirus B19

References

1. wilate® Product Monograph August 19, 2016. Octapharma Canada Inc.

Who is Octapharma?

Octapharma is one of the largest plasma product manufacturers in the world dedicated to the development and production of human proteins derived from blood plasma and recombinant technologies.

We are a company that brings:

- More than 30 years of experience in bleeding disorders
- Company owned plasma centres to facilitate the control of plasma supply used to produce wilate® and other protein products
- A long-standing commitment to improving pathogen safety of plasma derived products
- Commitment to improving patient care through research into new technologies
- Dedication to improving patient care through established partnerships with both hemophilia organizations in Canada and worldwide

Canadian Hemophilia Society

Phone (514) 848-0503
Toll-free 1(800) 668-2686
Fax (514) 848-9661
www.hemophilia.ca
chs@hemophilia.ca

World Federation of Hemophilia

Phone (514) 875-7944
Fax (514) 875-8916
www.wfh.org
wfh@wfh.org

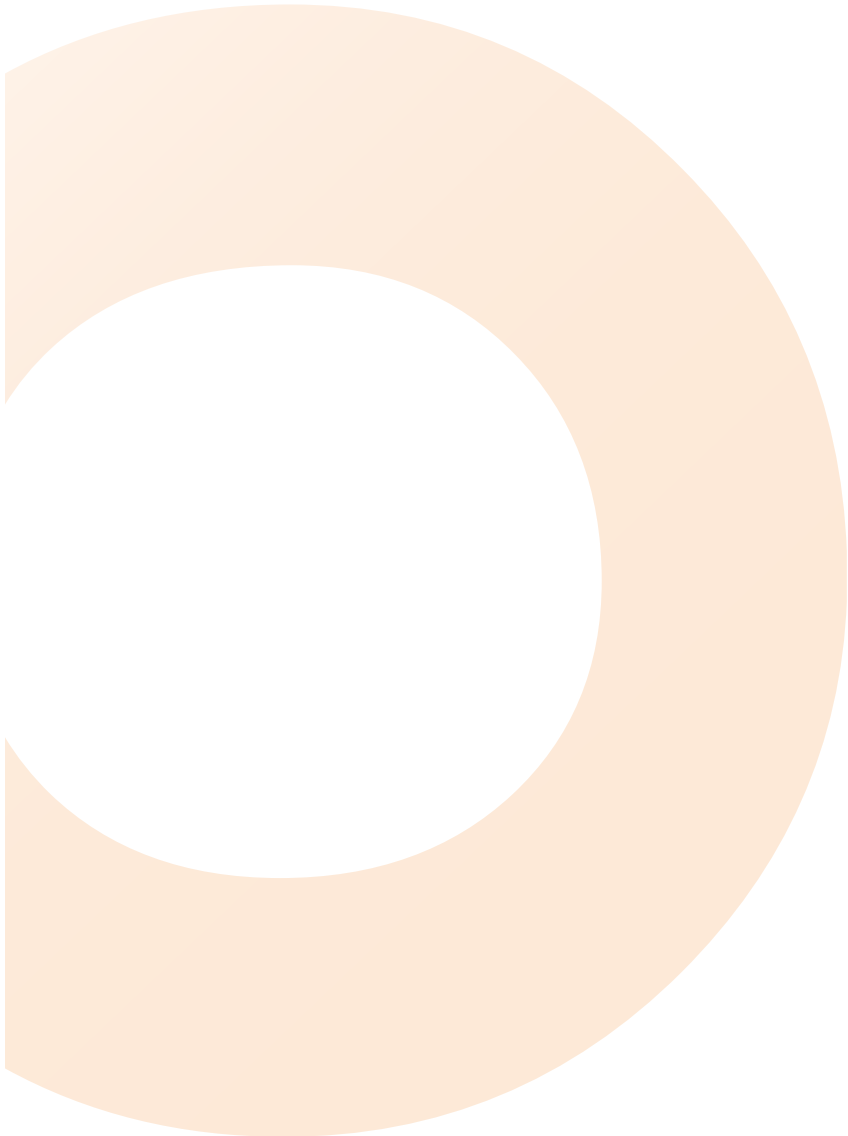
Association of Hemophilia Clinic Directors of Canada

Phone (416) 864-5042
Fax (416) 864-5251
www.ahcdc.ca
ahcdc@smh.ca

This booklet has been reviewed by Dr. Jean St-Louis of Hôpital Maisonneuve-Rosemont and Ann Marie Stain of Kiddies HealthCare Inc.

wilate® is a registered trademark of Octapharma AG
Mix2Vial™ is a trademark of Medimop Medical Projects Ltd
© 2017 Octapharma Canada Inc. All rights reserved.





Octapharma Canada Inc.
308-214 King Street West
Toronto, Ontario M5H 3S6
www.octapharma.ca

octapharma