

Developed to set new standards in von Willebrand disease treatment

wilate® provides a number of benefits to the patients:

- the first double virus inactivated¹ high purity VWF/FVIII concentrate now approved also for prevention of bleeding in major surgery in VWD patients, including the severe (type 3) VWD^{2,*}
- no albumin added as stabiliser¹
- VWF and FVIII close to the physiological ratio of 1 to 1^{1,3}
- excellent efficacy in treatment of acute bleedings in all types of VWD (excellent/good efficacy rating in 96% of treated bleeds)⁴
- proven efficacy in long term prophylaxis in VWD patients, including children⁴

wilate®

New generation
VWF/FVIII concentrate

octapharma

For the safe and optimal use of human proteins

NOW
APPROVED
ALSO FOR MAJOR
SURGERY



wilate® basic prescribing information*

Composition: The medicinal product contains per vial 450 IU/900 IU human coagulation factor VIII (FVIII) and 400 IU/800 IU human von Willebrand factor (VWF) prepared from human plasma for fractionation. Solvent: Water for Injections with 0.1% Polysorbate 80. wilate® 450 is dissolved in 5 ml, wilate® 900 is dissolved in 10 ml. Excipients: Sodium chloride, Glycine, Sucrose, Sodium citrate and Calcium chloride, Solvent (Water for injections with 0.1% Polysorbate 80). **Therapeutic Indications*:** Treatment and prevention of bleeding episodes, and treatment and prevention of bleeding in minor and major surgeries, in patients with von Willebrand disease (VWD) and haemophilia A (congenital or acquired FVIII deficiency). **Contra-Indications:** Hypersensitivity to the active substances or to any of the excipients. **Side effects:** See local Summary of Product Characteristics for details. **Precautions:** In rare occasions: fever, hypersensitivity or allergic reactions, in some cases progress to severe anaphylaxis (including shock). Patients with VWD, especially type 3 patients, may very rarely develop neutralising antibodies to VWF. Haemophilia A: Patients may rarely develop neutralising antibodies (inhibitors) to FVIII. Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. On prescription only. Octapharma AG, Seidenstrasse 2, CH-8853 Lachen, Switzerland, Version: October 2008

References

1. Stadler M et al., Characterisation of a novel high-purity, double virus inactivated von Willebrand Factor and Factor VIII concentrate (Wilate). *Biologicals* (2006), 34(4): 281-8.
2. indication approved by PEI on Sep 23, 2008
3. European Wilate prescribing information
4. Berntorp E et al., Treatment and prevention of acute bleedings in von Willebrand disease – efficacy and safety of Wilate, a new generation von Willebrand factor/factor VIII concentrate. *Haemophilia*, accepted for publication Aug 2008, in print

* Indications and other registration conditions differ from country to country. Please check nationally approved prescribing information. In Denmark the product is registered as wilnativ®, wilate® is not yet registered in the USA.

WILA.ADV.R.08/10.01.CPEN © Copyright 2008, Octapharma AG. All rights reserved.