TRANSFUSION MEDICINE PROTOCOLS

Factor VIII (8)

This document should be read in conjunction with the Disclaimer

Discuss ALL requests for Factor VIII with the Consultant Haematologist.

PRODUCT	Plasma Derived Factor VIII and von Willebrand Factor	Recombinant Factor VIII
FORMULATIONS	**Biostate®** Biostate® Product Information	**Xyntha®** Xyntha® Product information **Advate®** Advate® Product Information
SPECIFICATIONS	Biostate® is a high purity, sterile, powder for injection containing human coagulation factor VIII (FVIII) and von Willebrand factor (vWF) complex.	Recombinant Factor VIII (Antihaemophiliac factor). Does NOT contain von Willebrand Factor.
VIAL SIZE	**NOTE** vials state FVIII and vWF activity: 250 IU FVIII / 500IU vWF (5mL H_2O reconstitution) 500 IU FVIII / 1000IU vWF (10mL H_2O reconstitution) 1000 IU FVIII / 2000IU vWF (10mL H_2O reconstitution)	250, 500, 1000 and 2000 IU
INDICATIONS	Plasma derived Factor VIII and von Willebrand Factor is used for the management of bleeding episodes including surgical and dental procedures in patients with **von Willebrand's disease** and **Haemophilia A.**	Recombinant Factor VIII is the treatment of choice in the treatment of traumatic and spontaneous bleeds, perioperative management and prevention (prophylaxis) of bleeding in patients with **Haemophilia A** (Factor VIII deficiency).

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CONTRAINDICATIONS	**Biostate®** is contraindicated in individuals with a history of anaphylactic or severe systemic response to coagulation FVIII and/or vWF preparations. It is contraindicated in individuals with a known hypersensitivity to any of its components.	**Xyntha®:** Do not use in patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components including hamster proteins. **Advate®:** Do not use in patients who have life-threatening hypersensitivity reactions, including anaphylaxis, to mouse or hamster protein or other constituents of the product (mannitol, trehalose, sodium chloride, histidine, tris, calcium chloride, polysorbate 80, and/or glutathione).
CONSUMER INFORMATION	Biostate® Consumer Medicine Information	Xyntha® Consumer Medicine Information Advate® Consumer Medicine Information
CONSENT	Manufactured from pooled human plasma. Document as consent for blood product in medical record required. Refer to WNHS Blood Product Consent and Refusal	Not a blood product - consent for treatment.
ORDERING	Ordered on named patient basis from Transfusion Medicine Unit (TMU) and Haematologist	Ordered on named patient basis from TMU and Haematologist
DOSE	**Requests and dosage of all Factor VIII products must be discussed with the Consultant Haematologist.**	
PRESCRIPTION	**WARNING** Each prescription for Biostate should specify the 'active entity' of the ordered dose of both Factor VIII and von Willebrand Factor e.g. Biostate 1000iu of VWF Biostate 1500iu of FVIII Any order for Biostate that does not specify the 'active entity' of ordered dose should be clarified before the order is processed.	

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RECONSITUTION	⚠CAUTION For instructions on reconstitution/filtration, refer to the individual product information and other supporting material accompanying the product. Biostate® Reconstitution Guide Xyntha® Reconstitution Guide Advate® Reconstitution Guide For information on using the Mix2Vial™ Mix2Vial™ **Draw up as indicated on the instruction sheet. Use the accompanying diluent in the volume supplied for that vial.**	
ADMINISTRATION	• Two staff to perform checks as per the Clinical Practice Manual, WNHS Pharmacy Medication Checking and Administration processes. Check Issue label and patient ID. Check right patient, right product, right dose – prescription matches product supplied. If not identical, contact TMU • Verify that the prescription is complete, including clearly stating the type of Factor VIII. • Administered slowly by the IV route (usually within 5-6 mins, or as tolerated by the patient). The injection rate should not exceed 6mL/min. Rate as specified by prescribing MO • Biostate should be administered as slow push through syringe • Do not mix/piggy back product with other medications or IV fluids/blood products.	
OBSERVATIONS	• Administer Bolus doses under constant visual observation. • Vital signs (temperature, pulse, respiration, blood pressure) must be undertaken and recorded in the medical notes to enable the information to be retrieved later, it necessary. Observe for signs of any adverse reaction /tissue infiltration. • Monitor patient for at least 10 minutes post administration	
ADVERSE REACTIONS	Symptoms may include: skin rash, itching, tightness of throat or chest, shortness of breath, chest pain or wheezing. For more information refer to the Product Information. Adverse reaction should be reported to the Clinical Haematologist and TMU. Refer to WNHS Management of Transfusion Reactions and Adverse Events, as a guide to patient treatment and management.	
DOCUMENTATION	A record must be kept in the patient's medical notes of the following: • The date and time of administration & amount given	

	• The batch number and expiry date of each bottle used must be attached to the Blood Product Administration Record/ Transfusion Record MR735 (product has a peel off label with batch number and expiry date on). This information is important should the patient have a reaction or if there is a need to trace recipients of batch numbers at a later date.
For further information, refer to product insert. Return product to TMU immediately if no longer required. Use for intended patient (issue label) only.	

References

- Australian Red Cross Blood Service – Transfusion practice for health professionals. http://www.transfusion.com.au/blood_products/fractionated_plasma/immunoglobulins
- Advate® Product Information
- Biostate® Product Information
- Xyntha® Product Information
- The Australian Blood Service (ARCBS) Blood Component Information http://www.transfusion.com.au/sites/default/files/BCI%202009.pdf
- Flippin' Blood BloodSafe SA / ARCBS Second Edition June 2012 http://resources.transfusion.com.au/cdm/ref/collection/p16691coll1/id/20
- Guidelines for use of coagulation factors and management of haemophilia and other bleeding disorders (Australian Haemophilia Centre Directors' Organisation), are available at www.ahcdo.org.au/publications
- National Safety and Quality Health Service Standards, October 2012. Standard 7: Blood and Blood Products

Related WNHS policies, procedures and guidelines

- WNHS Blood Product Prescription, Consent and Refusal
- WNHS Management of Transfusion Reactions and Adverse Events
- WNHS Transfusion Equipment and Administration
- WNHS Pharmacy Medication Checking and Administration
- Neonatology Clinical Care Guidelines
- Obstetrics and Gynaecology Clinical Guidelines
- WNHS Pharmacy Medication Checking and Administration

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Standards Applicable:	NSQHS Standards: 1 Governance, 5 Patient ID/Procedure Matching, 7 Blood Products		
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