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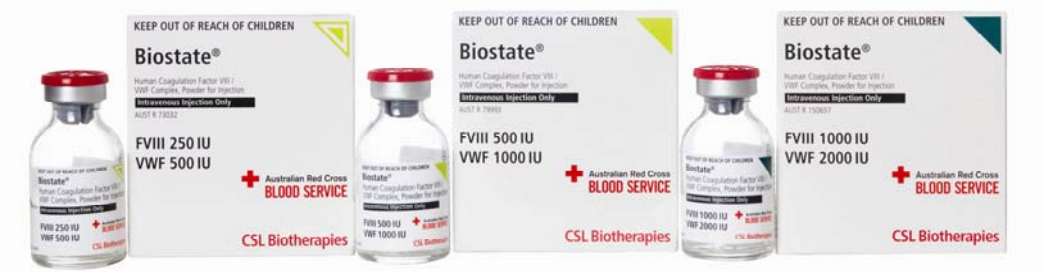
CSL Biotherapies

Australian Red Cross BLOOD SERVICE

4 November 2011
ref : CF11.50

Dear Colleague

Re: <u>BIOSTATE® 1,000 IU FVIII / 2,000 IU VWF</u> <u>supplied with 10mL WFI</u>



CSL Biotherapies and the Australian Red Cross Blood Service are pleased to advise availability of a larger and more concentrated presentation of BIOSTATE from Monday 21 November 2011 :-

BIOSTATE 1,000 IU factor VIII (FVIII) / 2,000 IU von Willebrand factor (VWF), supplied with 10mL water for Injections (100 IU/mL FVIII / 200 IU/mL VWF).

This presentation was developed by CSL Biotherapies to optimise treatment for people requiring larger doses of BIOSTATE, in response to requests from the bleeding disorders patient community and healthcare professionals.

Being both a larger and a more concentrated presentation than the existing two BIOSTATE presentations (see table overleaf), availability of this presentation will bring benefits to both patients and healthcare professionals.

Larger doses of BIOSTATE can be prepared from fewer vials and administered in a lower volume dose, thereby shortening reconstitution and infusion times for:-

- patients and carers who infuse BIOSTATE at home, and
- healthcare professionals who prepare and administer BIOSTATE in a hospital or clinic setting.

<u>BIOSTATE Presentations</u>

Three BIOSTATE presentations are currently registered and supplied in Australia :

BIOSTATE Presentation	Colour Wedge on Carton & Vial	WFI volume	Final Concentration[1] FVIII	VWF
BIOSTATE 250 IU FVIII / 500 IU VWF		5mL	50 IU/mL	100 IU/mL
BIOSTATE 500 IU FVIII / 1,000 IU VWF		10mL	50 IU/mL	100 IU/mL
BIOSTATE 1,000 IU FVIII / 2,000 IU VWF		10mL	100 IU/mL	200 IU/mL

[1] nominal

BIOSTATE Prescribing and Administration

In compliance with TGA requirements, the carton and vial of each BIOSTATE presentation clearly state both FVIII and VWF content. To support clarity in the prescribing, ordering and administration of BIOSTATE, CSL Biotherapies, the Australian Haemophilia Centre Directors' Organisation (AHCDO), the Australian Haemophilia Nurses Group (AHNG), and the Australian Red Cross Blood Service ***recommend that each order for BIOSTATE should specify the active entity (VWF or FVIII) of the ordered dose.***

Examples 'BIOSTATE - 1000 IU of VWF'
'BIOSTATE - 1500 IU of FVIII'

Additionally these organisations recommend that all centres that stock or administer BIOSTATE consider amending :

- *Clinical Practice Guidelines used by haematologists and in haemophilia treatment centres, and*
- *Dispensing protocols for BIOSTATE used in Blood Banks and/or Pharmacies*

such that both documents clearly state the following information for BIOSTATE :

1. BIOSTATE contains both FVIII and VWF in a 1:2 ratio, and is approved for use in both haemophilia A and von Willebrand disease

2. Each order for BIOSTATE should specify the active entity (VWF or FVIII) of the ordered dose (see examples above)

3. Any order for BIOSTATE that does not specify the active entity (VWF or FVIII) of the ordered dose should be clarified before the order is processed.

These recommendations are documented in the BIOSTATE Advisory Statement issued December 2010, which can be downloaded from The Blood Service's iTransfuse Express website at - http://www.transfusion.com.au/iTransfuse/express.

Should you have any questions regarding this information, please contact either CSL Biotherapies or the Blood Service in your state or territory.

Yours sincerely,

Dr Christopher Fry
Snr Product Manager
CSL Biotherapies

Dr Joanne Pink
Chief Medical Officer
Australian Red Cross Blood Service

Before prescribing please review the approved Product Information available on request from CSL Biotherapies

PBS Information: This product is not listed on the PBS. This product is funded under arrangements implemented by the National Blood Authority. Please refer to the National Blood Authority for details.

Minimum Product Information BIOSTATE® (Human coagulation factor VIII and human von Willebrand factor complex, powder for injection) **Indications:** The treatment of bleeding episodes including surgical bleeding in patients with von Willebrand disease when desmopressin treatment is ineffective or contraindicated. The treatment and prophylaxis of bleeding associated with factor VIII (FVIII) deficiency due to haemophilia A. **Contraindications:** Individuals with a history of anaphylactic or severe systemic response to coagulation FVIII and/or von Willebrand Factor (VWF) preparations. Known hypersensitivity to any components. **Precautions:** BIOSTATE® is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses and theoretically Creutzfeldt-Jakob Disease agents that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors and by dedicated virus removal and inactivation procedures included in the manufacturing process. Despite these safety measures, such products may still potentially transmit disease. Hepatitis A and hepatitis B vaccination for patients in receipt of medicinal products from human plasma should be considered where appropriate. BIOSTATE® should be used with caution in patients with known risk

factors for thrombosis and who are hypersensitive to FVIII, VWF or human albumin. Patients congenitally deficient in FVIII or VWF may develop neutralising antibodies (inhibitors) to FVIII or VWF respectively. The use of BIOSTATE® in pregnancy, lactation, paediatric and elderly populations has not been established in appropriate clinical studies. **Interactions**: The interaction of BIOSTATE® with other drugs has not been established in specific studies. **Adverse effects:** Allergic, anaphylactic reactions or fever are rarely observed in patients receiving FVIII/VWF preparations. In the case of an adverse event, the rate of injection should be slowed or stopped Headache, back, chest and skeletal pain, anxiety, arthralgia, dizziness, sweating, dyspnoea, thrombophlebitis, dysgeusia, syncope, abnormal liver function test, vomiting, nausea, pyrexia, flushing and fever have been reported. **Dosage and Administration:** The exact loading and maintenance doses and intervals based on patient's clinical condition and response to therapy. Calculated based on the patient's weight, the initial and desired circulating FVIII and/or VWF levels, and the duration of treatment. Refer to approved PI. BIOSTATE® does not contain an antimicrobial preservative and must be used within three hours after reconstitution. It must not be added or mixed with any other fluids to be given, including whole blood. Administer intravenously and slowly, within 5 minutes or as tolerated. Based on BIOSTATE® Approved Product Information, date of most recent amendment: 9 September 2010.(v 09/11)

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