ESSENTIAL INFORMATION (EI/CORE/ENGLISH)

BERIATE®

Based on the Company Core Package Insert (CCPI),
Rev.: 07-APR-2014 / Adaptation to FVIII Core-SPC, QRD, etc.

Supersedes previous version
Rev.: 18-JUN-2013 / 2000 IU
Rev.: 24-MAY-2011 / virus filtration / Mix2Vial
This is essential information only. For national prescribing information please see your country specific package insert that comes with the product.

It may be that the situation as given in the prescribing information specific for your country is different with regard to indications, contraindications, license holder etc. Please see your country-specific package insert or contact our local representative for further information.

1. Name

Beriate®

2. Composition

Powder and solvent for solution for injection or infusion containing nominally 250/500/1000/2000 IU human coagulation factor VIII per vial.
Other ingredients: Glycine, Calcium chloride, Sodium hydroxide (in small amounts) for pH adjustment, Sucrose, Sodium chloride.

3. Indications

Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency). This product may be used in the management of acquired factor VIII deficiency.

4. Contraindications

Hypersensitivity to the active substance or to any of the excipients.

5. Special warnings and special precautions for use

Allergic type hypersensitivity reactions are possible. Patients should be informed of the early signs of those reactions and should be advised to discontinue use of the product immediately and contact their physician.

Beriate contains up to 28 mg sodium per 1000 IU. To be taken into consideration by patients on a controlled sodium diet.
The formation of neutralising antibodies (inhibitors) to factor VIII is a known complication in the management of individuals with haemophilia A. These inhibitors are usually IgG immunoglobulins directed against the factor VIII procoagulant activity, which are quantified in Bethesda Units (BU) per ml of plasma using the modified assay. The risk of developing inhibitors is correlated to the exposure to factor VIII, this risk being highest within the first 20 exposure days. Rarely, inhibitors may develop after the first 100 exposure days.

Cases of recurrent inhibitor (low titre) have been observed after switching from one factor VIII product to another in previously treated patients with more than 100 exposure days who have a previous history of inhibitor development. Therefore, it is recommended to monitor all patients carefully for inhibitor occurrence following any product switch.

In general, all patients treated with human coagulation factor VIII should be carefully monitored for the development of inhibitors by appropriate clinical observations and laboratory tests. If the expected factor VIII activity plasma levels are not attained, or if bleeding is not controlled with an appropriate dose, testing for FVIII inhibitor presence should be performed. In patients with high levels of inhibitor, factor VIII therapy may not be effective and other therapeutic options should be considered. The management of such patients should be directed by physicians with experience in the care of haemophilia A patients and those with factor VIII inhibitors.

**Paediatric population**
The listed warnings and precautions apply both to adults and children.

**Pregnancy**
Beriate should be used during pregnancy and lactation only if clearly indicated.

**Virus safety**
Multiple measures to prevent infections are taken. However, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens.

The measures taken are considered effective for enveloped viruses such as HIV, HBV and HCV, and for the non-enveloped viruses such as HAV and parvovirus B19.

Appropriate vaccination (hepatitis A and hepatitis B) should be generally considered for patients in regular/repeated receipt of human plasma-derived factor VIII products.

### 6. Undesirable effects

Hypersensitivity or allergic reactions have been observed very rarely, and may in some cases progress to severe anaphylaxis (including shock). On very rare occasions, fever has been observed.
Patients with haemophilia A may very rarely develop neutralising antibodies (inhibitors) to factor VIII. If such inhibitors occur, the condition will manifest itself as an insufficient clinical response. In such cases, it is recommended that a specialised haemophilia centre be contacted.

Paediatric Population
Frequency, type and severity of adverse reactions in children are expected to be the same as in adults.

7. Prescription status

Prescription-only drug.

8. Manufacturer

CSL Behring GmbH
Emil-von-Behring-Str. 76
35041 Marburg
Germany

9. Date of information

April 2014