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# HELIXATE® FS Fact Sheet

## (Antihemophilic Factor [Recombinant])

**Product Description**

HELIXATE® FS (Antihemophilic Factor [Recombinant]) is a sterile, stable, purified, nonpyrogenic, dried product for the treatment of classical hemophilia (hemophilia A). HELIXATE® FS provides a means of temporarily replacing the missing clotting factor in order to correct or prevent bleeding episodes, or in order to perform emergency or elective surgery in people with hemophilia.[1]

**Indication**

HELIXATE® FS is indicated for the treatment of hemophilia A in which there is a demonstrated deficiency of activity of the plasma clotting factor VIII (FVIII). When used as a regular prophylactic treatment, HELIXATE® FS is also indicated to prevent the occurrence of spontaneous hemorrhagic episodes and to prevent joint damage in children with no pre-existing joint damage.[1]

**Mechanism of Action**

Patients who have hemophilia A do not have enough clotting Factor VIII (FVIII), which helps control bleeding. HELIXATE® FS, a recombinant clotting FVIII that has been developed in the laboratory, is very similar to the FVIII that occurs naturally in human blood. In patients with hemophilia A who do not have enough natural FVIII in their blood, HELIXATE® FS provides them with additional FVIII to help prevent and/or control bleeding.[1]

**Method of Administration**

HELIXATE® FS is administered directly into the blood through an injection in a vein, usually over 5 to 10 minutes. Patients may also receive treatment before surgery by an initial all-at-once injection followed immediately by continuous infusion. Available in vials containing 250 international units (IU), 500 IU, 1000 IU, 2000 and 3000 IU, HELIXATE® FS is supplied with a Mix2Vial* filter transfer set offering convenient administration with a 2.5 mL volume diluent. The 2000 and 3000 IU vial size requires a 5.0 mL volume diluent. Dosage is calculated based on weight, blood tests of FVIII levels, and whether HELIXATE® FS is being used to prevent or stop a bleeding episode.[1]

**Clinical Overview**

Two six-month studies with HELIXATE® FS demonstrated an excellent efficacy profile. A total of 73 patients with severe hemophilia A, ages 12-59, who had been previously treated with other recombinant/plasma-derived FVIII products were enrolled in two 6-month studies of home therapy with rFVIII-FS, one in Europe and one in North America.

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* Mix2Vial is a registered trademark of West or one of its subsidiaries.

During the study, a significant number (92.7 percent) of bleeding episodes were treated successfully with one or two infusions.[1]

**Safety Profile**

HELIXATE® FS is contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container, and in patients known hypersensitivity to mouse or hamster protein.

In clinical trials, HELIXATE® FS has been shown to be well tolerated when used in the treatment of patients with hemophilia A. Adverse events, such as local injection-site reaction, nausea, dizziness, and rash, were reported.

In clinical studies involving previously treated patients, no inhibitor formation was detected. In clinical studies involving previously untreated patients, 15 percent developed inhibitors to HELIXATE® FS. To date, there have been no confirmed cases of viral transmissions with HELIXATE® FS.

For complete risk / benefit profile as well as the full prescribing information of HELIXATE® FS please refer to the current Product Monograph / Prescribing Information, available on our website at www.cslbehring.ca.

Reference

1. HELIXATE® FS Product Monograph, January 27, 2010, CSL Behring Canada Inc.