Helixate® FS Antihemophilic Factor (Recombinant) Formulated with Sucrose

**INDICATIONS AND USAGE**

Helixate® FS Antihemophilic Factor (Recombinant) is indicated for the treatment of bleeding disorders arising from a deficiency in FVIII. This deficiency should be proven prior to administering Helixate® FS. The treatment of circulating neutralizing antibodies to FVIII may occur during the treatment of patients with hemophilia A. Inhibitor formation is especially common in young children with severe hemophilia during their first 3 years of treatment, or in patients of any age who have received little previous treatment with FVIII. Nonetheless, inhibitor formation may occur at any time in the treatment of a patient with hemophilia A. Patients treated with any AHI preparation, including Helixate® FS, should be carefully monitored for the development of antibodies. This may be accomplished by appropriate clinical evaluation and laboratory tests, according to the recommendation of the patient’s hemophilia treatment center.

Among patients treated with antihemophilic factor concentrates, cases of hypotension, urticaria, and chest tightness have been associated with hypersensitivity reactions. In rare cases of allergic and anaphylactic reactions have been reported with the predecessor product HELIXATE® Antihemophilic Factor (Recombinant), patients who have previously reacted to HELIXATE may be at increased risk of a similar reaction.

**CONTRAINDICATIONS**

Known hypersensitivity to mouse or hamster protein may be a contraindication to the use of Helixate FS.

**WARNINGS**

None.

**PRECAUTIONS**

**General**

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**Post-marketing experience**

The following events are principally derived from post-marketing experience and publications, and accurate incidence rates are generally not possible. Among pediatric patients treated with recombinant FVIII products, very rare cases of serious allergic reactions and anaphylactic reactions have been reported, particularly in very young patients or patients who had previously reacted to other FVIII concentrates. Individual cases of hypotension have been very rarely reported. Rare cases of urticaria have also been reported. Although such serious reactions have not been reported with the use of Helixate FS, it is likely that these may also occur. Rare cases of dyspnea have been reported with Helixate FS.

**DOSAGE AND ADMINISTRATION**

Each bottle of Helixate FS has the FVIII potency in international units stated on the label based on the one-stage assay methodology. The reconstituted product must be administered within 3 hours after reconstitution.

**INDICATIONS AND USAGE**

Helixate® FS is indicated for the treatment of classical hemophilia (hemophilia A) in which there is a demonstrated deficiency of activity of the plasma clotting factor FVIII. Helixate® FS provides a means of temporarily replacing the missing clotting factor in order to correct or prevent bleeding episodes, in order to perform an elective surgery in hemophiliacs.

In clinical studies with previously untreated patients (PUPs), the reconstituted product HELIXATE, some patients who developed inhibitors on study continued to manifest a clinical response when inhibitor titer were less than 10 Bethesda Units (BU) per mL. When an inhibitor is present, the dosage requirement for FVIII is variable. The dosage can be determined only by clinical response, and by monitoring circulating FVIII levels after treatment [see DOSAGE AND ADMINISTRATION]. Because Helixate® FS has similar biological activity to HELIXATE it can be used in the same manner.

Helixate® FS does not contain von Willebrand’s factor and therefore is not indicated for the treatment of von Willebrand’s disease.

**CONTRAINDICATIONS**

Known hypersensitivity or allergic reactions to constituents of the preparation. Known hypersensitivity to mouse or hamster protein may be a contraindication to the use of Helixate FS.

**WARNINGS**

None.

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**GENERAL APPROACH TO TREATMENT AND ASSESSMENT OF TREATMENT EFICACY**

The dosages described below are presented as general guidance. It should be emphasized that the dosage of Helixate FS required for hemostasis must be individualized according to the needs of the patient, the severity of the bleeding, the severity of the hemorrhage, the presence of inhibitors, and the FVIII level desired. It is often critical to follow the course of therapy with FVIII level assays. The clinical effect of FVIII is the most important element in evaluating the effectiveness of treatment. It may be necessary to administer more FVIII than estimated to achieve a satisfactory clinical result. The dosage of FVIII is limited to the amount of FVIII that will be used in the following 24 hours. If a patient has been receiving FVIII for 24 hours, the amount of FVIII that will be administered in the following 24 hours must be at least 30 units/kg. If a patient has been receiving FVIII for more than 24 hours, the amount of FVIII that will be administered in the following 24 hours must be at least 50 units/kg.

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Surgery

hemarthroses, known trauma

into muscles, hemorrhages

into joints)

(superficial, early hemorrhages,

Hemorrhagic event

Therapeutically necessary

plasma level of FVIII activity

Dosage necessary to maintain the therapeutic

plasma level

Minor hemorrhage

(supraperitoneal, joint hemorrhages)

20–40%

10–20 IU/kg per kg

Repeat dose if evidence of further bleeding.

Moderate to major hemorrhage

(hemorrhages into muscles, hemorrhages

into the oral cavity, definite

hemorrhages, known trauma)

30–60%

15–30 IU/kg per kg

Repeat dose at 12–24 hours if needed.

Surgery

(major surgical procedures)

Major to life-threatening hemorrhage

(extraocular, extraoral or

intraocular hemorrhages, bleeding

causing visual loss, systemic

bleeding, bleeding in the

intracranial, intraspinal, or

intraventricular spaces, or

intracranial, or intraspinal, or

intraventricular spaces, or

intraparenchymal or retroperitoneal bleeding)

80–100%

Initial dose 40–50 IU/kg per kg

Repeat dose 20–25 IU/kg every 8–12 hours.

Prophylaxis

Self-injection

Prophylaxis may also be administered on a regular schedule for prophylaxis of bleeding, as reported by Nilsson et al.

Instructions for Use

Reconstitution and product administration must be done with caution. Perforate puncture with a needle

sized to allow as much blood as possible to enter the vial. Do not shake.

Reconstitution

Always wash your hands before performing the following procedures:

Vacuum Transfer

1. Place the vial in a 100 mL vial and fill it with saline.

2. Place the vial in a 500 mL Erlenmeyer flask and fill

3. Place the vial in a 500 mL Erlenmeyer flask and fill

4. Place the vial in a 500 mL Erlenmeyer flask and fill

5. Place the vial in a 500 mL Erlenmeyer flask and fill

6. Place the vial in a 500 mL Erlenmeyer flask and fill

7. Place the vial in a 500 mL Erlenmeyer flask and fill

8. Place the vial in a 500 mL Erlenmeyer flask and fill

9. Place the vial in a 500 mL Erlenmeyer flask and fill

10. Place the vial in a 500 mL Erlenmeyer flask and fill

11. Place the vial in a 500 mL Erlenmeyer flask and fill

12. Place the vial in a 500 mL Erlenmeyer flask and fill

Expected % factor VIII increase =

units administered x 2%/IU/kg

body weight (kg)

Example for a 70 kg adult

1400 IU x 2%/IU/kg

70 kg

= 40%

Example for a 15 kg child

15 kg x 100%

= 750 IU required

2%/IU/kg

The dosage necessary to achieve hemostasis depends on the type and severity of the bleeding episode, according to the following guidelines:

NDC Number Approximate FVIII Activity (IU) Dosage Diluent (mL)

0053-8130-01 250 2.5

0053-8130-02 500 2.5

0053-8130-04 1,000 2.5

L - Low

M - Med

H - High

STORAGE

Helixate FS is stored in a refrigerator at 2–8°C (36–46°F) for up to 3 months, such as in home treatment situations. Do not freeze. Do not use beyond the expiration date indicated on the bottle. Protect from extreme exposure to light and store the lyophilized powder in the carton prior to use.

CAUTION

Only for use in patients with acquired hemophilia A.

Helixate FS is supplied in the following single use bottles. A suitable volume of Sterile Water for Injection, USP and Mix2Vial® filter transfer set are provided. The actual potency is printed on the label and the carton.

REFERENCES


50, 1982.


50, 1982.