**INDICATIONS AND USAGE**

Recombinant, Fc Fusion Protein with Hemophilia A (congenital Factor VIII deficiency) for:

1. **Dose**
   - The dose of ELOCTATE should be administered intravenously at a rate of no less than 0.5 IU/kg/min.
   - The maximum rate of administration for routine prophylaxis is 30 IU/kg over 60 minutes.
   - For on-demand treatment and control of bleeding episodes:
     - The expected increment of Factor VIII levels can be monitored using either plasma (e.g., one-stage factor assay) or clotting factor assay.
     - To achieve a plasma Factor VIII level of 20-80 IU/dL, a dose of 0.08-0.12 IU/kg may be required.
     - For children <6 years of age, the recommended starting regimen is 50 IU/kg of body weight.

2. **Contraindications**
   - Hypersensitivity, including anaphylaxis, to any component of ELOCTATE or any other clotting factor therapy.
   - Active intravascular coagulation.
   - Central nervous system hemorrhage.
   - Intracranial hemorrhage.
   - Intraspinal hemorrhage.
   - Acute (within 48 hours) or severe (within 1 week) bleeding.

3. **Warnings and Precautions**
   - Development of Factor VIII neutralizing antibodies may occur. The relevance of these data to humans is unknown. The detection of antibodies that are reactive to Factor VIII is highly sensitive, but not specific, for the development of inhibitors. Inhibitory antibodies may develop in subjects who respond properly to Factor VIII replacement therapy.

4. **Adverse Reactions**
   - The most frequent adverse reactions include:
     - Headache
     - Arthralgia
     - Myalgia
     - Local injection site reaction

**Dosage and Administration**

**How Supplied/Storage and Handling**

**References**

**Table 1: Adverse Reactions Reported During ELOCTATE Use**

<table>
<thead>
<tr>
<th>System</th>
<th>Body Site</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GI</strong></td>
<td>Abdomen</td>
<td>4 (1.4)</td>
</tr>
<tr>
<td><strong>Skin</strong></td>
<td>Rash</td>
<td>2 (0.9)</td>
</tr>
<tr>
<td><strong>Musculoskeletal</strong></td>
<td>Muscle pain</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td><strong>Skin</strong></td>
<td>Pruritus</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td><strong>Infections</strong></td>
<td>CNS Infections</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td><strong>Blood and lymphatic</strong></td>
<td>Hemorrhage, retroperitoneum</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td><strong>Local</strong></td>
<td>Injection site reaction</td>
<td>1 (0.4)</td>
</tr>
</tbody>
</table>

**Table 2: Dosing for Routine Prophylaxis Management**

- **Dosing**
  - The recommended prophylactic dosing is 100 IU/kg every 24 hours for children 6 to 18 years of age.
  - For patients aged <6 years, the recommended starting regimen is 50 IU/kg.

- **Monitoring Laboratory Tests**
  - The plasma Factor VIII level should be monitored at least weekly during the first 3 months of therapy, then every 3 months, and then annually.

- **Table 3: Dosing for Prophylactic Management**

- **Dosing**
  - The recommended prophylactic dosing is 100 IU/kg every 24 hours for children 6 to 18 years of age.
  - For patients aged <6 years, the recommended starting regimen is 50 IU/kg.

**Table 4: Dosing for Treatment of Bleeding Episodes**

- **Dosing**
  - The recommended dosing for treatment of bleeding episodes is 100 IU/kg every 12 hours for children 6 to 18 years of age.
  - For patients aged <6 years, the recommended starting regimen is 50 IU/kg.

**Table 5: Dosing for Hemophilia A Routine Prophylaxis**

- **Dosing**
  - The recommended prophylactic dosing is 100 IU/kg every 24 hours for children 6 to 18 years of age.
  - For patients aged <6 years, the recommended starting regimen is 50 IU/kg.

**Table 6: Dosing for Hemophilia A On-Demand Treatment**

- **Dosing**
  - The recommended dosing for on-demand treatment is 100 IU/kg every 12 hours for children 6 to 18 years of age.
  - For patients aged <6 years, the recommended starting regimen is 50 IU/kg.

**Table 7: Dosing for Hemophilia A Routine Prophylaxis**

- **Dosing**
  - The recommended prophylactic dosing is 100 IU/kg every 24 hours for children 6 to 18 years of age.
  - For patients aged <6 years, the recommended starting regimen is 50 IU/kg.

**Table 8: Dosing for Hemophilia A On-Demand Treatment**

- **Dosing**
  - The recommended dosing for on-demand treatment is 100 IU/kg every 12 hours for children 6 to 18 years of age.
  - For patients aged <6 years, the recommended starting regimen is 50 IU/kg.
**11 DESCRIPTION**

Bleeding Factor VIII, activated (Fc Fusion Protein), N.T.C. Factor VIII, is a plasma-protein product, to be infused subcutaneously for replacement therapy in patients with Hemophilia A (factor VIII deficiency) for the prevention and treatment of bleeding episodes. ELOCTATE is indicated for the prophylaxis of hemostasis during perioperative management in subjects undergoing surgical procedures. The study enrolled a total of 71 previously treated male pediatric patients for prophylaxis in routine daily practice settings.

**12 PHARMACOKINETICS**

Thromboplastinia 1 is a bleeding disorder characterized by a deficiency of factor Xa. Activated clotting factor Xa, resulting in a prolonged partial thromboplastin time (P TT), has also been associated with this disorder. The P TT abnormality is due to a deficiency of factor Xa.

**13 CLINICAL PHARMACOLOGY**

The safety and efficacy of ELOCTATE were evaluated in less than 12 years of age, and in adults and adolescents (aged 12 to 17 years) in the adult and adolescent study and for adolescents (aged 12 to 17 years) in the extension study. There were no dose adjustments based on age, weight or body surface area. There were no changes in dosing between age groups. 64% of subjects received a dose of 25-80 IU/kg. There were no statistically significant differences in any PK parameters among dose levels.