RECOMBINE
Antithrombin Factor (Recombinant)

Prothrombinase: a synthesizer

Please read this leaflet carefully before you start treatment with RECOMBINE. Antithrombin Factor (Recombinant). This leaflet is based on the information provided to your doctor and is a summary of the important information you should know about your medicine for your factor VIII deficiency. This leaflet does not take the place of talking with your doctor and does not contain all of the information available about RECOMBINE. This summary should be read only after you have been started on treatment with your doctor's or pharmacist.

1. How to take RECOMBINE

Factor VIII (also called antithrombin factor) is the clotting factor that helps people with hemophilia A form a bleeding diathesis that prevents clots from forming within the body. All people with hemophilia A are born with the disorder. Frequently, people with hemophilia A are found to be healthy and dawing the disease in their 30s, because the abnormalities can be concealed. An inherited clotting disorder may lead to the symptoms. Patients may experience a variety of symptoms, including difficulty breathing and (or) lasting arterial pressure. In rare cases, the disorder may cause unexpected death.

Polymorphism: a synthesizer

2. What are the possible side effects of RECOMBINE? The most common side effects include itching, nausea, vomiting, fever, chills, new age, and bone, back and heart. In rare cases, the disorder may cause unexpected death. In rare cases, the disorder may cause unexpected death. In rare cases, the disorder may cause unexpected death.

3. How do I use RECOMBINE? RECOMBINE, Antithrombin Factor (Recombinant) (FVIII) is injected directly into the body. Other treatments your doctor may choose to use are blood plasma or clotting factor concentrates. These treatments are used to prevent bleeding or to treat bleeding episodes. They can be given by the following routes of administration: intravenous (IV), subcutaneous (SC), or intramuscular (IM).

4. What to do if your reconstitution of the solution is not equal to the stated concentration.

5. What are the possible side effects of RECOMBINE? The most common side effects include itching, nausea, vomiting, fever, back and heart. In rare cases, the disorder may cause unexpected death. In rare cases, the disorder may cause unexpected death. In rare cases, the disorder may cause unexpected death. In rare cases, the disorder may cause unexpected death.

6. What to do if your reconstitution of the solution is not equal to the stated concentration.

In the event of anaphylactoid reactions, patients with hemophilia A are at risk for anaphylactic reactions. Although the majority of these reactions are mild, severe reactions such as anaphylactic shock can result in death.

7. What to do if your reconstitution of the solution is not equal to the stated concentration.

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**Information for Patients**

**Recombinant Antithrombin Factor (Recombinant)**

**Proascalopramone sodium and heparin-bonded factor X concentrates**

**Precautions**

Read this carefully before starting your treatment with RECOMBINANT ANTIHUMAN PLASMA CLUTING FACTOR X (Recombinant) (AHF). This product is labeled based on the information provided by your doctor and is a summary of the most important information you should know about your future treatment.

**Blood clots**

Blood clots, also called thrombi, are clumps of blood that form in blood vessels. They can block blood flow and cause pain, swelling, and tissue damage. Blood clots can be caused by many factors, including injuries, infections, and certain medical conditions.

**Antithrombin factor (AHF)**

Antithrombin factor (AHF) is a protein that helps prevent blood clots. It works by inhibiting the activity of certain blood clotting enzymes. AHF is used to treat people with a deficiency of this protein, which can lead to an increased risk of blood clots.

**Recombinant AHF**

Recombinant AHF is produced in the laboratory using genetically modified human cells. It is made to have the same properties as human AHF and is intended to be used as a treatment for people with a deficiency of AHF.

**Thrombosis and embolism**

Thrombosis is the formation of blood clots in a blood vessel. Embolism is the blocking of a blood vessel by a blood clot or other material. Both conditions can be serious and may require treatment.

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**Patients**

Patients should be advised to discuss the risks and benefits of this product with their doctor.

**Laboratory and diagnostic tests**

The effects of the medication as well as the duration of the treatment may vary depending on the individual patient.

**Clotting factor (AHF)**

Clotting factor (AHF) is a protein that helps prevent blood clots. It works by inhibiting the activity of certain blood clotting enzymes. AHF is used to treat people with a deficiency of this protein, which can lead to an increased risk of blood clots.

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**Recommended Storage Conditions**

- May be refrigerated or shipped at 2°C–8°C (36°F–46°F) or stored at room temperature up to 30°C (86°F) for short periods of time.
- Reconstituted concentrate solutions are stable at room temperature up to 30°C (86°F) for 15 minutes.
- The concentrate should be kept away from direct sources of heat or light.

**Storage**

- **Reconstituted concentrate solutions** can be stored at room temperature up to 30°C (86°F) for 15 minutes.
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Recommended Drug Reactions

Pharmacologic name of the drug is required. The following dosage schedule may be used as a guide.

**Dosage**

<table>
<thead>
<tr>
<th>Route</th>
<th>Dosage</th>
<th>Frequency</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>IM</td>
<td>50-100</td>
<td>q2-4h</td>
<td>1-4 days</td>
</tr>
<tr>
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<td>50-100</td>
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**Type of Injection**

- Injection: skin, subcutaneous, intramuscular, intradermal, intradermal.
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**Storage**

- Reconstituted concentrate must be refrigerated during transportation and storage.
- Use reconstituted concentrate within 4 hours of reconstitution.
- Reconstituted concentrate must be used within 24 hours of reconstitution.
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**Preparation of Reconstituted Concentrate**

1. The reconstituted concentrate is a sterile, pyrogen-free, USP-grade product.
2. Reconstituted concentrate is prepared by mixing 1 vial of concentrate with 1 mL of diluent.
3. Reconstituted concentrate is a clear, colorless solution.
4. Reconstituted concentrate is used within 24 hours of reconstitution.

**Route of Administration**

- Intravenous injection: intravenous injection is recommended for use with this product since protection is needed for all patients with hemophilia.
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**How Supplied**

- Reconstituted concentrate is supplied in a vial of concentrate. Each vial contains 1 vial of concentrate and 1 vial of diluent.
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**References**


**Important Information**

- Contact your hemophilia treatment center for more information and resources.
- Ensure that all patients who have been treated with this product are maintained on a 12-hour dosing schedule.
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