

## Patient Information

### TRETTEN®

#### Coagulation Factor XIII A-Subunit (Recombinant)

This leaflet summarizes important information about TRETTEN. Please read it carefully before using TRETTEN and each time you get a refill because there may be new information provided. This information does not take the place of talking with your healthcare provider, and it does not include all of the important information about TRETTEN. If you have any questions after reading this, ask your healthcare provider.

#### **What is TRETTEN?**

TRETTEN is an injectable medicine used to prevent bleeding in adults and children who have congenital factor XIII (FXIII) A-subunit deficiency. TRETTEN is man-made and does not contain animal or human materials.

#### **Who should not use TRETTEN?**

You should not use TRETTEN if you have ever had allergic (hypersensitivity) reactions, including severe, whole body reaction (anaphylaxis) to TRETTEN or any of the ingredients.

#### **What should I tell my healthcare provider before TRETTEN is given?**

Tell your healthcare provider about all of your medical conditions, including:

- If you are pregnant, think you may be pregnant or planning to become pregnant. It is not known if TRETTEN can harm you or your unborn baby.
- Labor and Delivery: It is not known if TRETTEN is safe and effective during labor and delivery.
- Breast feeding: It is not known if TRETTEN passes into your breast milk.
- If you have a history of blood clots.

Tell your healthcare provider about all of the medicines you take, including all prescription and non-prescription medicines such as over-the-counter medicines, supplements, or herbal remedies.

#### **How is TRETTEN given?**

TRETTEN is given as an injection into your vein (intravenous injection). These injections are given once a month.

Your dose will depend on your body weight. Use the dose that your healthcare provider has prescribed for you based on your weight.

Before injecting TRETEN, it must be dissolved (reconstituted) using the sterile water that is provided in the package. Throw away any TRETEN left in the vial after you inject your dose because it may become unsterile.

### **What are the possible side effects of TRETEN?**

Call your healthcare provider or go to the emergency department right away if you have any of the following symptoms after using TRETEN:

- Signs of allergic reaction including
  - shortness of breath
  - rash
  - itching (pruritus)
  - redness of the skin (erythema)
  - fainting/dizziness
- Signs of a blood clot including pain, swelling, warmth, redness, or a lump in your legs or arms, chest pain, or sudden severe headache and/or loss of consciousness or function
- Unexpected bleeding

Other possible side effects may include:

- pain in your arms or legs
- headache
- pain at the injection site

These are not all the possible side effects of TRETEN. Tell your healthcare provider about any side effect that bothers you or that does not go away. You can also report side effects to the Food and Drug Administration (FDA) at 1-800-FDA-1088.

### **How should I store TRETEN?**

It is important to store TRETEN correctly.

#### **Before preparing TRETEN for injection**

Keep TRETEN in a refrigerator at 36°F to 46°F (2°C to 8°C) and in the original package in order to protect it from light. Do not freeze TRETEN.

#### **After preparing TRETEN for injection (reconstituted)**

Use TRETEN immediately after it is dissolved (reconstituted) using the sterile water provided in the package.

If you cannot inject it immediately, either leave TRETEN at room temperature not above 25°C (77°F) or put TRETEN in the refrigerator at 36°F to 46°F (2°C to 8°C) for no more than 3 hours. After more than 3 hours, DO NOT USE IT—THROW IT AWAY.

TRETEN does not contain a preservative. Do not store TRETEN in the syringe or placed in the freezer.

### **What else should I know about TRETEN?**

Do not use TRETEN for a condition for which it is not prescribed. Do not share TRETEN with other people, even if they have the same symptoms that you have.

Talk to your healthcare provider if you would like more information.

### **TRETEN ingredients include:**

- Coagulation Factor XIII A-Subunit (Recombinant)
- Sodium Chloride
- Sucrose
- Polysorbate 20
- L-Histidine

TRETEN and the sterile water vials provided in the package are not made with natural rubber latex.

This Patient Package Insert has been approved by the US Food and Drug Administration

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