## Recombinant Factor VIII

### Indications
- Control and prevention of bleeding episodes in adults and children with hemophilia A (congenital factor VIII deficiency).
- Control and prevention of bleeding episodes in adolescents and adults with hemophilia A who have a history of inhibitors.
- Control and prevention of bleeding episodes in adolescents and adults with severe von Willebrand disease.
- Perioperative management to control and prevent bleeding episodes in adult and pediatric patients with hemophilia A.
- Perioperative management to treat and control bleeding episodes in adult and pediatric patients with severe von Willebrand disease.

### Contraindications
- Hypersensitivity reactions to ADVATE, ELOCTATE, or any of their excipients.
- Patients with a history of life-threatening anaphylaxis to human, hamster, or bovine proteins.

### Nutrient in Cell Culture
- Trypsin (including traces of hamster proteins).
- Albumin.
- Albumin.

### Viral Removal Process
- The purification process includes a series of chromatography steps in which the monoclonal antibody directed against the FVIIIc protein is captured on a protein A affinity column.
- The ADVATE molecule is then eluted under mild conditions in a high purity form and further purified by membranes.

### Nutrient in Cell Culture
- Cell culture medium which does not contain any proteins derived from bovine, mouse, or hamster sources.
- CHO cell line but does not contain plasma or animal origin proteins.

### Nutrient in Cell Culture
- CHO cell line.

### Storage Requirements
- Product as packaged for sale: Store ADVATE at 2° to 8°C (35° to 45°F) in the original package to protect from light. Store under recommended storage conditions.
- Storage at room temperature: Do not store at room temperature for extended periods, as it may affect efficacy.

### Shelf Life from Date of Manufacture
- 30 months

### Dicoumarol Volumes
- 750 IU, 2.5 mL, 1000 IU, 2.5 mL, 1500 IU, 5 mL, 3000 IU, 5 mL

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### Table: Recombinate vs Advate

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<th>Product Specifications</th>
<th>Kogenate® FS</th>
<th>Advate</th>
<th>NovoEight®</th>
<th>ELOCTATE™</th>
<th>XYNTHA®</th>
<th>Helixate® FS</th>
<th>Recombinate</th>
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