### Antithrombin/Protein C

#### Product Specs

<table>
<thead>
<tr>
<th></th>
<th>ATryn</th>
<th>Thrombate-III®</th>
<th>CEPROTIN</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
<td>ATryn is a recombinant antithrombin indicated for the prevention of peri-operative and peri-partum thromboembolic events in hereditary antithrombin deficient patients. It is not indicated for treatment of thromboembolic events in hereditary antithrombin deficient patients.</td>
<td>Treatment of patients with hereditary antithrombin III deficiency in connection with surgical or obstetrical procedures or when they suffer from thromboembolism.</td>
<td>For pediatric and adult patients with severe congenital Protein C deficiency for the prevention and treatment of venous thrombosis and purpura fulminans.</td>
</tr>
<tr>
<td><strong>Contraindications</strong></td>
<td>Unknown hypersensitivity to goat and goat milk proteins.</td>
<td>None known</td>
<td>None known</td>
</tr>
<tr>
<td><strong>Source of Antithrombin</strong></td>
<td>Recombinant human antithrombin produced through recombinant DNA technology using genetically engineered goats. DNA sequence directs the antithrombin expression into goat's milk.</td>
<td>Plasma derived. Thrombate III is made from large pools of human plasma donated at centers with the US.</td>
<td>Protocoll is the precursor of a thrombin-dependent anticoagulant glycoprotein (aortic protease) that is synthesized in the liver. It is converting to the thrombomodulin complex of the endothelial cell surface to activated Protein C (APC), APC is a vitamin K-dependent glycoprotein with proteolytic and regulatory effects, especially in the presence of its cofactor protein S.</td>
</tr>
<tr>
<td><strong>Viral Safety Process</strong></td>
<td>Tangential Flow Filtration, Affinity Chromatography, Nanofiltration ion Exchange Chromatography, Hydrophobic Interaction Chromatography, Heat Treatment. Log10 reductions range from greater than or equal to greater than or equal to 20.0 log.</td>
<td>Heat treatment in solution at 60°C for not less than 10 hours. Nanofiltration for effective removal of viruses as small as 18 nm.</td>
<td>Combination of filtration and chromatographic procedures, including a column of immobilized mouse monoclonal antibodies on gel beads.</td>
</tr>
<tr>
<td><strong>Route of Administration</strong></td>
<td>May be administered intravenously via sterile syringe or via an infusion bag</td>
<td>Bolus intravenous infusion (over 10-20 minutes)</td>
<td>May be administered intravenously via sterile syringe or via an infusion bag</td>
</tr>
<tr>
<td><strong>Product Half-Life</strong></td>
<td>15.0 days</td>
<td>Initial Half-Life (mean): 5.4 to 6.3</td>
<td>Initial Half-Life (mean): 5.9 to 7.4</td>
</tr>
<tr>
<td><strong>Shelf Life from Date of Manufacture</strong></td>
<td>5 years</td>
<td>3 years</td>
<td>3 years</td>
</tr>
<tr>
<td><strong>Shelf Life After Reconstitution</strong></td>
<td>24 hours</td>
<td>5 hours</td>
<td>5 hours</td>
</tr>
<tr>
<td><strong>Storage Requirements</strong></td>
<td>+ Refrigerated between 2°C and 8°C (36°F-46°F). + Do not use product beyond the expiration date printed on the package. + Do not freeze.</td>
<td>+ Store at room temperature not to exceed 2°C (37°F). + Do not freeze.</td>
<td>+ Refrigerated between 2°C and 8°C (36°F-46°F) for up to 5 years. + Do not freeze.</td>
</tr>
<tr>
<td><strong>Diluent Volume</strong></td>
<td>525 IU/3.2 mL</td>
<td>500 IU/5 mL</td>
<td>500 IU/10 mL</td>
</tr>
<tr>
<td><strong>Available Vial Sizes</strong></td>
<td>525 IU for the 3.2 mL vial and 1750 IU 20 mL vial size</td>
<td>500 IU</td>
<td>500 or 1000 IU per vial</td>
</tr>
</tbody>
</table>
A Group Purchasing Organization (GPO) Activities
- Agreements with all major manufacturers for clotting factor product purchases
- Substantial member savings on clotting factor product purchases
- Letters of support from Manufacturers for the HTC participation in the 340B Drug Program

Hemophilia Alliance Membership Support and Activities
- Funded with revenue from group purchasing agreements
- Bi-annual member meetings providing policy and practice updates
- Webinar series with topics including:
  - Development of inhibitors in Hemophilia A
  - Moving into the age of Novel Therapies
  - Caregiver Burden and Hemophilia

Advocacy Activities
- Annual Advocacy Day in Washington, DC to educate Congress about HTCs and 340B
- Relationships built with 340B Program, HRSA/MCH, and Medicaid Officials
- Participation in coalition efforts with other grantees and hospitals participating in 340B Program
- Analysis of and strategic responses developed regarding legislative and regulatory proposals impacting HTCs participating in 340B

HTC Support
HTC operational support services provided by consultants with expertise in:
- Pharmacy operations
- Public and private insurance practices
- Compliance and other legal issues
- 340B Policies and Procedures

Hemophilia Community Activities
Support and collaborate with other national hemophilia organizations including:
- National Hemophilia Foundation (NHF)
- Hemophilia Federation of America (HFA)
- American Thrombosis and Hemostasis Network (ATHN)
- Thrombosis and Hemostasis Societies of North America (THSNA)
- Hemophilia Alliance Foundation
- Alliance for Integrated Medicine Management (AIMM)
- World Federation of Hemophilia (WFH)

Hemophilia Alliance Product Guide

Hemophilia Alliance Product Guide

FVIII/vWF Complex Concentrates

<table>
<thead>
<tr>
<th>Product Specs</th>
<th>Alphanate®</th>
<th>Humate-P®</th>
<th>Vonvendi</th>
<th>Wilate®</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Surgical and/or major procedures in adult and pediatric patients with von Willebrand disease who require treatment (SMDR) in other indications or contraindicated.</td>
<td>Von Willebrand disease (VWD) in adults and pediatric patients in the (5) Treatment of spontaneous and trauma-induced bleeding episodes, and (2) Prevention of excessive bleeding during and after surgery.</td>
<td>On-demand treatment and control of bleeding episodes in adults diagnosed with von Willebrand disease.</td>
<td>On-demand treatment and control of bleeding episodes.</td>
</tr>
<tr>
<td></td>
<td>It is not indicated for prophylaxis of spontaneous bleeding episodes in VWD.</td>
<td>This applies to patients with VWD as well as patients with mild to moderate VWD where the use of desmopressin is known or suspected to be inadequate. Hemate-P is not indicated for the prophylaxis of spontaneous bleeding episodes in VWD.</td>
<td>Wilate is not indicated for treatment for hemophilia A.</td>
<td>Prevention of management of bleeding.</td>
</tr>
<tr>
<td>Contraindications</td>
<td>Do not use in patients who have manifest ed life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components.</td>
<td>Do not use in patients who have had life-threatening hypersensitivity reactions to VONVENDI or its components (human, hamster, or mouse proteins).</td>
<td>Patients with known hypersensitivity reactions such as anaphylactic or severe systemic reactions, to human plasma-derived product, any ingredient in the formulation or components of the container.</td>
<td></td>
</tr>
<tr>
<td>Ratio of vWF: RCo to FVIII</td>
<td>Ratio by lot</td>
<td>2.41</td>
<td>1.8</td>
<td>1.8</td>
</tr>
<tr>
<td>Viral Removal &amp; Inactiva tion Process</td>
<td>Afresh Chromatography, 5,5’-Sialyloligosaccharides, native glycoprotein precipitate, afresh precipitation, solvent/detergent precipitation, and lyophilisate, resulting in 14.5% FVIII:C: 19.6 ± 0.5%; 1.3:1 Ratio of vWF: RCo to FVIII.</td>
<td>Viral inactivation steps: Protein A affinity chromatography, 3.5% PEG precipitation, salt/glycine terminal dry-heat treatment of the lyophilized product in final container at 80°C (176°F) for 120 minutes at a specified residual heating rate of 5°C (9°F) per minute.</td>
<td>No human or animal derived proteins are used in the manufacturing process.</td>
<td>Rimex-chromatography, solvothermic treatment, and terminal dry heat treatment of the lyophilized product in final container at 145°C (293°F) for 80 minutes at a specified residual heating rate of 5°C (9°F) per minute.</td>
</tr>
<tr>
<td>Product Half-Life</td>
<td>7.9 ± 0.5 hours</td>
<td>8.4 ± 4.0 hours</td>
<td>10 ± 0.5</td>
<td>10 ± 0.5</td>
</tr>
<tr>
<td>Product Recovery Percentage</td>
<td>98 ± 1.1%</td>
<td>98 ± 1.1%</td>
<td>98 ± 0.4%</td>
<td>98 ± 0.4%</td>
</tr>
<tr>
<td>Storage Requirements</td>
<td>Room temperature not to exceed 25°C (77°F).</td>
<td>Room temperature not to exceed 25°C (77°F).</td>
<td>Room temperature not to exceed 25°C (77°F).</td>
<td>Room temperature not to exceed 25°C (77°F).</td>
</tr>
<tr>
<td>Shelf Life from Date of Manufacture</td>
<td>12 months at room temperature</td>
<td>12 months at room temperature</td>
<td>12 months at room temperature</td>
<td>12 months at room temperature</td>
</tr>
<tr>
<td>Diluent Volume</td>
<td>250, 500, 1000 IU/5 mL</td>
<td>250, 500 IU/5 mL</td>
<td>250, 500 IU/5 mL</td>
<td>250, 500 IU/5 mL</td>
</tr>
</tbody>
</table>

FVIII/vWF Complex Concentrates

Product guide for Hemophilia A and von Willebrand disease treatments, showing indications, contraindications, product specifications, and storage requirements. The table compares Alphanate, Humate-P, Vonvendi, and Wilate, highlighting their respective uses, concentrations, and storage conditions.
The Hemophilia Alliance Foundation was established in 2009 by the Hemophilia Alliance. Since its inception in 2006, the Hemophilia Alliance intended to dedicate its discretionary revenue to nonprofit organizations serving the bleeding disorders communities. In 2009 the Alliance established a grants committee which awarded a total of $250,000 to eligible national, regional and local organizations. Since 2009 the Foundation has awarded over $3.5 million.

The grants committee comprised diverse individuals with experience in the bleeding disorders communities. In 2013, The Hemophilia Alliance Foundation was established as a nonprofit corporation in Pennsylvania, and was given 501(c) (3) tax exempt status by the U.S. Internal Revenue Service. Its volunteer board of directors reviews and decides on grants applications.

In addition to its support from the Hemophilia Alliance, the Hemophilia Alliance Foundation is now also supported by funding from The Alliance Pharmacy.

Non-profit organizations serving people with bleeding disorders are eligible to apply for funding. In 2016, the support for programs was a maximum of $6,000. Chapters could also apply for an additional $5,000 to be used for patient assistance awards.

Grant applications are accepted once each year, reviewed by the volunteer board of directors, and awarded in March for the April 1–March 31 grant year. For more information about the process and requirements, see the grant guidance at www.hemophiliaalliancefoundation.org.

Plasma-Derived Factor VIII

### Indications
- Treatment of classical hemophilia (hemophilia A) in which there is a demonstrated deficiency of activity of the plasma clotting factor, factor VIII.
- Treatment of von Willebrand disease in patients with hemophilia A.
- Prevention of excessive bleeding during and after surgery.

### Contraindications
- Do not use in patients who have manifested life-threatening anaphylactic or anaphylactoid reactions, including angioedema, to the product or its components.
- Known hypersensitivity to the active substance, excipients or active protein.

### Source Plasma
- Pooled human plasma
- Pooled plasma

### Viral Removal & Inactivation Process
- Precipitation with 3.5% polyethylene glycol (PEG), heat treatment (60°C, 24 hours), lyophilization; aluminum hydroxide treatment followed by heat treatment at 60°C for 10 hours in aqueous solution.
- Cryoprecipitation; immunoaffinity chromatography; ion exchange chromatography; solvent/detergent, dry heat treatment (80°C, 72 hours).

### Product Half-Life (hours)
- VWF:RCo, 6.91 (range: 3.8 to 16.22)
- FVIII:C 20.92 (range: 7.19 to 32.2)

### Product Recovery Percentage
- 1.9 units/dL rise/U/kg 10 minutes postinfusion
- 2.8 IU/kg rise per 10 kg

### Presence of von Willebrand Factor
- Yes

### Storage Requirements
- Room temperature not to exceed 25°C (77°F).
- Do not freeze.
- Refrigerated at 2°C-8°C (36°F-46°F), or room temperature (up to 25°C or 77°F).
- Do not freeze.

### Shelf Life from Date of Manufacture
- 3 years

### Diluent Volume
- 500 IU FVIII/5 mL
- 1000 IU FVIII/10 mL
- 2000 IU FVIII/10 mL
- 1200 IU VWF:RCo/10 mL
- 1000 IU FVIII/15 mL
- 500 IU FVIII/10 mL

### Diluent Volume
- 3.5% polyethylene glycol
- 1.0% polysorbate 80
- Sodium chloride
- Aluminum hydroxide
### Plasma-Derived Factor IX

#### Product Specs

<table>
<thead>
<tr>
<th>Brand</th>
<th>Alphamine® SD</th>
<th>Bebulin</th>
<th>Mononine®</th>
<th>Profilnine®</th>
</tr>
</thead>
</table>

**Indications**

- The prevention and control of bleeding episodes in adult patients with hemophilia A or B, or Factor VIII deficiency.
- The prevention and control of bleeding in Factor IX deficiency, also known as hemophilia B or Christmas Disease.
- Treatment of Factor IX deficiency due to hemophilia B.
- The prevention and control of bleeding episodes in adult patients with inhibitors to Factor IX.

**Contraindications**

- Known history of heparin-induced thrombocytopenia.
- Known history of heparin-induced thrombocytopenia.

**Viral Removal & Inactivation Process**

- BEBULIN is not indicated for use in the treatment of Factor VII deficiency.
- Mononine is not indicated in the treatment or reversal of coumarin anticoagulant-induced anticoagulation or in a hemorrhagic state caused by hepatitis-induced lack of production of liver-dependent coagulation factors.

**Storage Requirements**

- Refrigerated at 2°C-8°C (36°F-46°F), or room temperature up to 25°C (77°F).
- Do not freeze.

**Shelf Life from Date of Manufacture**

- 3 years, or 1 month at room temperature.

**Diluent Volume**

- 5 mL for 500 IU, 10 mL for 1000 & 1500 IU.

**Percentage**

- 1.23 ± 0.16 IU/dL per IU infused per kg body weight.

**Percentage**

- 35.7 ± 9.5%.

**Percentage**

- 53.24% ± 21.8%.

**Percentage**

- 57.5% ± 21.8%.

**Percentage**

- 65.7% ± 8.29%.

**Percentage**

- 95.3 ± 3.2.

**Percentage**

- 89.6 ± 1.2.

**Percentage**

- 9.6% ± 0.16 IU/dL per IU infused per kg body weight.

**Percentage**

- 9.6 ± 0.29.

**Percentage**

- 34.8 ± 2.5 IU/dL.

**Percentage**

- 44.8 ± 2.5 IU/dL.

**Percentage**

- 52.2 ± 2.5 IU/dL.

**Percentage**

- 57.5 ± 2.5 IU/dL.

**Percentage**

- 57.5 ± 2.5 IU/dL.

**Percentage**

- 57.5 ± 2.5 IU/dL.
Recombinant Factor VIII

<table>
<thead>
<tr>
<th>Product Specs</th>
<th>ADVATE</th>
<th>Helixate® FS</th>
<th>Kogenate® FS</th>
<th>Novoeight®</th>
<th>Recombinate</th>
<th>XYNTHA®</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Adults: Control and prevention of bleeding episodes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Perioperative management</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Routine prophylaxis to prevent or reduce the frequency of bleeding episodes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td><strong>Therapeutic value in patients with acquired factor VII inhibitors not exceeding 10 Bethesda Units per mL</strong></td>
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<tr>
<td><strong>Contraindications</strong></td>
<td>Nutrient in Cell Culture</td>
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<tr>
<td>Do not use in patients who have life-threatening hypersensitivity reactions, including anaphylaxis, to mouse or hamster protein or other constituents of the product.</td>
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<tr>
<td>Do not use in patients who have life-threatening hypersensitivity reactions, including anaphylaxis, to mouse or hamster proteins, including bovine, mouse or hamster proteins.</td>
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<tr>
<td>Do not use in patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to Novoeight or its components, including bovine, mouse or hamster proteins.</td>
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<tr>
<td>Do not use in patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including bovine, mouse or hamster proteins.</td>
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<tr>
<td><strong>Stabilizer in Final Formulation</strong></td>
<td></td>
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<tr>
<td>Sodium, sucrose, glucose, histidine</td>
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<tr>
<td>Sodium, glycine, histidine, sodium, calcium chloride, polysorbate 80, and sodium chloride</td>
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<tr>
<td>Sodium, glycine, histidine, sodium, calcium chloride, polysorbate 80, imidazole, tri-n-butyl phosphate, and copper</td>
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<tr>
<td><strong>Viral Removal &amp; Inactivation Process</strong></td>
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<tr>
<td>Ion exchange chromatography, monoclonal antibody immunoaffinity chromatography, solvent/detergent nanofiltration</td>
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<tr>
<td><strong>Product Half-Life (hours)</strong></td>
<td>12.0 ± 4.1</td>
<td>11.9 ± 1.92</td>
<td>11.8 ± 1.92</td>
<td>12.0 ± 4.1</td>
<td>14.6 ± 4.0</td>
<td>14.6 ± 4.0</td>
</tr>
<tr>
<td><strong>Product Recovery Percentage</strong></td>
<td>23 ± 0.5</td>
<td>23 ± 0.5</td>
<td>23 ± 0.5</td>
<td>23 ± 0.5</td>
<td>23 ± 0.5</td>
<td>23 ± 0.5</td>
</tr>
<tr>
<td><strong>Storage Requirements</strong></td>
<td>Refrigerated at 2°C-8°C (36°F-46°F), or room temperature up to 30°C (86°F).</td>
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<tr>
<td>Do not freeze.</td>
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<tr>
<td>Refrigerated at 2°C-8°C (36°F-6°F), or room temperature up to 25°C (77°F).</td>
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<td>Do not freeze.</td>
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<tr>
<td>Refrigerated at 1°C-4°C (34°F-39°F), or room temperature up to 37°C (99°F).</td>
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<tr>
<td>Do not freeze.</td>
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<tr>
<td>Refrigerated at 1°C-4°C (34°F-6°F), or room temperature up to 32°C (89°F).</td>
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<tr>
<td>Do not freeze.</td>
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<tr>
<td>Do not freeze.</td>
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</tr>
<tr>
<td><strong>Shelf Life from Date of Manufacture</strong></td>
<td>24 months, or 4 months at room temperature</td>
<td>24 months, or 4 months at room temperature</td>
<td>24 months, or 4 months at room temperature</td>
<td>24 months, or 4 months at room temperature</td>
<td>24 months, or 4 months at room temperature</td>
<td>24 months, or 4 months at room temperature</td>
</tr>
<tr>
<td><strong>Diluent Volume</strong></td>
<td>2 mL, 4 mL</td>
<td>250, 500, 1000 IU/4.5 mL</td>
<td>250, 500, 1000 IU/4.5 mL</td>
<td>250, 500, 1000 IU/4.5 mL</td>
<td>250, 500, 1000 IU/4.5 mL</td>
<td>250, 500, 1000 IU/4.5 mL</td>
</tr>
</tbody>
</table>

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**Hemophilia Alliance Product Guide**

**Recombinant Factor VIII (continued)**

<table>
<thead>
<tr>
<th>Product Spec</th>
<th>ADYNOVATE</th>
<th>AFSTYLA*</th>
<th>ELOCTATE®</th>
<th>KOVALTRY®</th>
<th>NUWIQ</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ADYNOVATE</strong>, Antihemophilic Factor (Recombinant), PEGylated, is a recombinant, antihemophilic factor.</td>
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<tr>
<td><strong>AFSTYLA</strong>, Antihemophilic Factor (Recombinant), Single Chain, is a recombinant, antihemophilic factor.</td>
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<tr>
<td><strong>ELOCTATE</strong>, Antihemophilic Factor (Recombinant), Frh Fusion Protein, is a recombinant B-domain deleted B-domain derived, antihemophilic factor.</td>
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<td></td>
</tr>
<tr>
<td><strong>KOVALTRY</strong>, Antihemophilic Factor (Recombinant), is a recombinant, human DNA sequence-derived, single B-domain-derived, antihemophilic factor.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>NUWIQ</strong> is a recombinant, B-domain deleted antihemophilic factor.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Indications**

**Adults:**
- On-demand treatment and control of bleeding episodes
- Perioperative prophylaxis to reduce the frequency of bleeding episodes
- Routine prophylaxis to reduce the frequency of bleeding episodes
- On-demand treatment and control of bleeding episodes

**Children:**
- On-demand treatment and control of bleeding episodes
- Perioperative prophylaxis
- Routine prophylaxis

**Contraindications and Nutrient in Cell Culture**

**Stabilizer in Final Formulation**

**Viral Removal & Inactivation Process**

**Product Half-Life (hours)**

**Product Recovery Percentage**

**Storage Requirements**

**Shelf Life from Date of Manufacture**

**Diluent Volume**

*Note: Terminal half-life is the time required to divide the plasma concentration by two after reaching pseudo-equilibrium, and not the time required to eliminate half the administered dose. (Toutain PL, et al. J Vet Pharmacol Ther. 2004.)*
## Recombinant Factor IX

### Product Specs

<table>
<thead>
<tr>
<th>ALPROLIX®</th>
<th>BeneFIX®</th>
<th>IDELVION®</th>
<th>IXINITY®</th>
<th>RIXUBIS</th>
</tr>
</thead>
</table>
| **Indications** | • Control and prevention of bleeding episodes in adults and children.  
• Perioperative management in adults and children.  
• Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children. | • Control and prevention of bleeding episodes in adults and children.  
• Perioperative management in adults and children.  
• Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children. | • Control and prevention of bleeding episodes.  
• Perioperative management of bleeding.  
• Routine prophylaxis to prevent or reduce the frequency of bleeding episodes.  
• Terminal half-life: 83.59 hours in adolescents 12-17 years.  
• Terminal half-life: 86.52 hours in adults ≥12 years of age with hemophilia B. | • Control and prevention of bleeding episodes.  
• Perioperative management of bleeding.  
• Routine prophylaxis to prevent or reduce the frequency of bleeding episodes.  
• Mean incremental recovery in (IU/dL)/(IU/kg) 0.67 (±0.15) for 36 months from the date of manufacture. |

### Adults:

- **Control and prevention of bleeding episodes:** Yes  
- **Perioperative management:** Yes  
- **Routine prophylaxis to prevent or reduce the frequency of bleeding episodes:** Yes

### Children:

- **Control and prevention of bleeding episodes:** Yes  
- **Perioperative management:** Yes  
- **Routine prophylaxis to prevent or reduce the frequency of bleeding episodes:** Yes

### Contraindications

- **Nanofiltration, column chromatography:** IDELVION is not indicated for induction of immune tolerance in patients with hemophilia B. Do not use in patients who have had life-threatening hypersensitivity reactions to IDELVION or its components, including hamster protein.
- **Chromatography, solvent/detergent treatment, nanofiltration:** Do not use in patients who have had life-threatening hypersensitivity reactions to IDELVION or its components, including hamster protein.
- **Chromatography, solvent/detergent:** Do not use in patients who have had life-threatening hypersensitivity reactions to IDELVION or its components, including hamster protein.
- **Nanofiltration, column chromatography, solvent/detergent:** Do not use in patients who have had life-threatening hypersensitivity reactions to IDELVION or its components, including hamster protein.

### Viral Removal & Inactivation Process

- **Nanofiltration, column chromatography:** The content of included Factor IX: fusion protein (FIXa) is <0.05 IU/mL as determined by bioassay and radioimmunoassay.  
- **Chromatography, nanofiltration, solvent/detergent:** IDELVION is not indicated for induction of immune tolerance in patients with hemophilia B. Do not use in patients who have had life-threatening hypersensitivity reactions to IDELVION or its components, including hamster protein.
- **Solvent/detergent treatment, nanofiltration:** IDELVION is not indicated for induction of immune tolerance in patients with hemophilia B. Do not use in patients who have had life-threatening hypersensitivity reactions to IDELVION or its components, including hamster protein.
- **Nanofiltration:** Do not use in patients with known hypersensitivity to IXINITY or its excipients including hamster protein.

### Product Half-Life

- **Terminal half-life:** 83.59 hours in adolescents 12-17 years.  
- **Mean recovery:** 0.98 IU/dL per IU/kg (±0.15) for 24 months.  
- **Mean recovery:** 0.98 IU/dL per IU/kg (±0.15) for 24 months.

### Product Recovery Percentage

- **Adults:** 0.8929 IU/dL per IU/kg  
- **Adolescents:** 0.8929 IU/dL per IU/kg

### Manufacturing Method

- **ALPROLIX® as a recombinant Factor IX:** A purified protein produced by recombinant DNA technology.
- **BeneFIX® as a recombinant Factor IX:** A purified protein produced by recombinant DNA technology.
- **IDELVION® as a recombinant Factor IX:** A purified protein produced by recombinant DNA technology.
- **IXINITY® as a recombinant Factor IX:** A purified protein produced by recombinant DNA technology.
- **RIXUBIS® as a recombinant Factor IX:** A purified protein produced by recombinant DNA technology.

### Storage Requirements

- **ALPROLIX®:** Store at 2°C-8°C (36°F-46°F) or at room temperature, not to exceed 30°C (86°F) for a single 6 month period. Do not use beyond the shelf life (36°C ± 2.7°C) for up to 12 months within the 24 month time period. Write on the carton the date the product was removed from refrigeration. Do not return the product to the refrigerator. Do not exceed the shelf life indicated on the carton or vial.
- **BeneFIX®:** Store at 2°C-8°C (36°F-46°F) or at room temperature, not to exceed 30°C (86°F) for a single 6 month period. Do not use beyond the shelf life (36°C ± 2.7°C) for up to 12 months within the 24 month time period. Write on the carton the date the product was removed from refrigeration. Do not return the product to the refrigerator. Do not exceed the shelf life indicated on the carton or vial.
- **IDELVION®:** Store at 2°C-8°C (36°F-46°F) or at room temperature, not to exceed 30°C (86°F) for a single 6 month period. Do not use beyond the shelf life (36°C ± 2.7°C) for up to 12 months within the 24 month time period. Write on the carton the date the product was removed from refrigeration. Do not return the product to the refrigerator. Do not exceed the shelf life indicated on the carton or vial.
- **IXINITY®:** Store at 2°C-8°C (36°F-46°F) or at room temperature, not to exceed 30°C (86°F) for a single 6 month period. Do not use beyond the shelf life (36°C ± 2.7°C) for up to 12 months within the 24 month time period. Write on the carton the date the product was removed from refrigeration. Do not return the product to the refrigerator. Do not exceed the shelf life indicated on the carton or vial.
- **RIXUBIS®:** Store at 2°C-8°C (36°F-46°F) or at room temperature, not to exceed 30°C (86°F) for a single 6 month period. Do not use beyond the shelf life (36°C ± 2.7°C) for up to 12 months within the 24 month time period. Write on the carton the date the product was removed from refrigeration. Do not return the product to the refrigerator. Do not exceed the shelf life indicated on the carton or vial.

### Shelf Life from Date of Manufacture

- **ALPROLIX®:** 6 months from the date of manufacture.
- **BeneFIX®:** 6 months from the date of manufacture.
- **IDELVION®:** 24 months.
- **IXINITY®:** 24 months under refrigerated; up to 12 months at room temperature.
- **RIXUBIS®:** 24 months under refrigerated; up to 12 months at room temperature.

### Diluent Volume

- **ALPROLIX®:** 5 mL  
- **BeneFIX®:** 5 mL of SWI supplied with each packaged kit
- **IDELVION®:** 5 mL  
- **IXINITY®:** 5 mL  
- **RIXUBIS®:** 5 mL
Rho(D) Immune Globulin

**Product Specs**

<table>
<thead>
<tr>
<th>HyperRho S/D</th>
<th>RhoGAM®</th>
<th>Rhophylac®</th>
<th>WinRho SDF Liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
<td>For prevention or treatment of Rh(D) sensitization</td>
<td>Pregnancy and other obstetric conditions in Rh-negative women unless the father or fetus is Rh-positive</td>
<td>Suppression of Rh immunization in Rh-negative women with an Rh-incompatible pregnancy; Suppression of Rh immunization in Rh-negative women with an Rh-incompatible transfusion.</td>
</tr>
<tr>
<td><strong>Contraindications</strong></td>
<td>Newborns, Rh(D)-negative infants (Hemolytic Disease of the Newborn), and Rh-negative women of childbearing age.</td>
<td>Individual with a history of anaphylactic or severe systemic reactions to human immune globulin products; Individuals with a history of anaphylaxis or severe systemic reaction to human immune globulin products; Individuals with a history of anaphylaxis or severe systemic reaction to human immune globulin products; Individuals with a history of anaphylaxis or severe systemic reaction to human immune globulin products.</td>
<td>None known. Rho(D) Immune Globulin (Human) should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human immune globulin products.</td>
</tr>
<tr>
<td><strong>Viral Safety Process</strong></td>
<td>Precipitation, depth ultrafiltration, solvent/detergent treatment.</td>
<td>Sterilization, filtration (post-batch filtration) and solvent/detergent treatment removes and inactivates both enveloped and non-enveloped viruses including Hepatitis A and West Nile.</td>
<td>Solvent/detergent and nanofiltration, anion exchange column chromatography.</td>
</tr>
<tr>
<td><strong>Route of Administration</strong></td>
<td>Intravenous.</td>
<td>Intravenous.</td>
<td>Intravenous.</td>
</tr>
<tr>
<td><strong>Clearance of Rh-positive Red Blood Cells</strong></td>
<td>Each single dose syringe contains sufficient anti-Rho(D) to effectively suppress the immunizing potential of 2.5 mL of Rho(D)-positive packed red blood cells or the equivalent of whole blood (5 mL).</td>
<td>Each single dose syringe contains sufficient anti-Rho(D) to effectively suppress the immunizing potential of 5 mL of Rh-positive packed red blood cells. (15 \text{ mL packed red blood cells} )</td>
<td>At least 15 mL of Rh-positive RBCs.</td>
</tr>
<tr>
<td><strong>Product Half-Life</strong></td>
<td>Approx. 23-25 days.</td>
<td>16 days for PF administration; 18-21 days for IM administration.</td>
<td>A 1500 IU dose will suppress the immunizing potential of approximately 15 mL of Rh-positive RBCs.</td>
</tr>
<tr>
<td><strong>Latex Content</strong></td>
<td>No.</td>
<td>No.</td>
<td>No.</td>
</tr>
<tr>
<td><strong>Thimerosal Content</strong></td>
<td>No.</td>
<td>No.</td>
<td>No.</td>
</tr>
<tr>
<td><strong>Storage Requirements</strong></td>
<td>Refrigerated at 2°C-8°C (36°F-46°F).</td>
<td>Refrigerated at 2°C-8°C (36°F-46°F).</td>
<td>Refrigerated at 2°C-8°C (36°F-46°F).</td>
</tr>
<tr>
<td><strong>Shelf Life from Date of Manufacture</strong></td>
<td>2 years</td>
<td>2 years</td>
<td>2 years</td>
</tr>
<tr>
<td><strong>How Supplied</strong></td>
<td>Prefilled syringe, ready to use.</td>
<td>Prefilled syringe, ready to use.</td>
<td>Prefilled syringe, ready to use.</td>
</tr>
<tr>
<td><strong>Available Sizes</strong></td>
<td>Max Dose: 250 IU prefilled disposable syringe in 10pk.</td>
<td>Full Dose: 2 mL prefilled syringe in 10pk.</td>
<td>1500 IU (300 mcg) RhoGAM Ultra-Filtered PLUS package sizes:</td>
</tr>
</tbody>
</table>

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**Member Benefits**

- Newsletter
- Reimbursement Expertise
- Alliance Purchasing Services Discounts
- Advocate in Washington, DC
- State Medicaid Policy and Billing Expertise
- Establishment of Pharmacy Program
- Management Experience
- Legal and Regulatory Compliance Advice
- Development of HTCL Policies and Procedures
- Member Meetings
- Updates via Webinars
- Participation in Federal Regulatory Process
## Additional Factor Concentrates

<table>
<thead>
<tr>
<th>Product</th>
<th>Factor X</th>
<th>Factor XIII</th>
<th>Factor Viia &amp; Anti-Inhibitor Complex</th>
<th>Fibrinogen Concentrate</th>
<th>Stimate® (Rose-Baaspray)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coagadex®</td>
<td>Corifact®</td>
<td>Tretten®</td>
<td>Feiba</td>
<td>NovoSeven® RT</td>
<td>Obizur</td>
</tr>
<tr>
<td>Indications</td>
<td>Adults and children (≥ 2 years and above) with hemophilia A or B deficiencies</td>
<td>Coagulant activity (CA) levels greater than 5% controls and prevents bleeding.</td>
<td>For use in hemophilia A and B patients with inhibitors.</td>
<td>For the treatment of bleeding episodes in adults with acquired hemophilia A.</td>
<td>For the treatment of acute bleeding episodes in patients with coagulation Factor VIII deficiencies.</td>
</tr>
<tr>
<td>Contraindications</td>
<td>Patients who have had life-threatening anaphylactic reactions to GM2200 or any of its components</td>
<td>None known.</td>
<td>None known.</td>
<td>None known.</td>
<td>None known.</td>
</tr>
<tr>
<td>Storage Requirements</td>
<td>Stored at 2°C to 8°C.</td>
<td>Stored at 2°C to 8°C.</td>
<td>Stored at 2°C to 8°C.</td>
<td>Stored at 2°C to 8°C.</td>
<td>Stored at 2°C to 8°C.</td>
</tr>
<tr>
<td>Shelf Life From Date of Manufacture</td>
<td>30 months</td>
<td>28 months, or 6 months at room temperature</td>
<td>35 months</td>
<td>Listed on label</td>
<td>Not listed on label</td>
</tr>
<tr>
<td>Diluent Volume</td>
<td>2 mL (50 IU/2.5 mL)</td>
<td>2 mL (50 IU/2.5 mL)</td>
<td>2 mL (50 IU/2.5 mL)</td>
<td>1 mL (250 IU/2.5 mL)</td>
<td>0.5 mL (125 IU)</td>
</tr>
</tbody>
</table>

### Coagadex®
- **Factor VIII activity level:** 140 to 300 IU/mL
- **Coagulant activity levels:** Greater than 5%
- **Indications:**
  - For use in hemophilia A and B patients with inhibitors
  - For the treatment of bleeding episodes in adults with acquired hemophilia A

### Corifact®
- **Factor VII (FVII) deficiency, and perioperative management in patients with hemophilia A with episodes of spontaneous or trauma-induced injuries such as hemarthroses, intramuscular hematomas, or nasal or oral bleeding.**

### Tretten®
- **Factor IX (FIX) deficiency, and perioperative management in patients with hemophilia A with episodes of spontaneous or trauma-induced injuries such as hemarthroses, intramuscular hematomas, or nasal or oral bleeding.**

### Feiba
- **Factor VII (FVII) deficiency, and perioperative management in patients with hemophilia A with episodes of spontaneous or trauma-induced injuries such as hemarthroses, intramuscular hematomas, or nasal or oral bleeding.**

### NovoSeven® RT
- **Factor VII (FVII) deficiency, and perioperative management in patients with hemophilia A with episodes of spontaneous or trauma-induced injuries such as hemarthroses, intramuscular hematomas, or nasal or oral bleeding.**

### Obizur
- **Factor VII (FVII) deficiency, and perioperative management in patients with hemophilia A with episodes of spontaneous or trauma-induced injuries such as hemarthroses, intramuscular hematomas, or nasal or oral bleeding.**

### Stimate® (Rose-Baaspray)
- **Factor VII (FVII) deficiency, and perioperative management in patients with hemophilia A with episodes of spontaneous or trauma-induced injuries such as hemarthroses, intramuscular hematomas, or nasal or oral bleeding.**

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**Feiba**
- **Listed on label**
- **Not listed on label**
- **Listed on label**
- **Listed on label**
- **Listed on label**

**NovoSeven® RT**
- **Listed on label**
- **Listed on label**
- **Listed on label**
- **Listed on label**
- **Listed on label**

**Obizur**
- **Listed on label**
- **Listed on label**
- **Listed on label**
- **Listed on label**
- **Listed on label**

**Stimate® (Rose-Baaspray)**
- **Listed on label**
- **Listed on label**
- **Listed on label**
- **Listed on label**
- **Listed on label**

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**Coagadex®**
- **Factors VIII and IX activities levels:** 140 to 300 IU/mL
- **Coagulant activity levels:** Greater than 5%
- **Indications:**
  - For use in hemophilia A and B patients with inhibitors
  - For the treatment of bleeding episodes in adults with acquired hemophilia A

**Corifact®**
- **Factor VII (FVII) deficiency, and perioperative management in patients with hemophilia A with episodes of spontaneous or trauma-induced injuries such as hemarthroses, intramuscular hematomas, or nasal or oral bleeding.**

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