

# Recombinant FVIII Products Facts and Features

PRODUCT NAME	NUWIQ® Antihemophilic Factor (Recombinant)	ELOCTATE® [Antihemophilic Factor (Recombinant), Fc Fusion Protein]	JIVI® [Antihemophilic Factor (Recombinant), PEGylated-auc]	AFSTYLA® Antihemophilic Factor (Recombinant), Single Chain	KOVALTRY® [Antihemophilic Factor (Recombinant)]	ADYNOVATE® Antihemophilic Factor (Recombinant), PEGylated	NOVOEIGHT® Antihemophilic Factor (Recombinant)	XYNTHA® (Antihemophilic Factor [Recombinant])	ADVATE® [Antihemophilic Factor (Recombinant)]	HELIXATE® FS [Antihemophilic Factor (Recombinant)]  KOGENATE® FS (Antihemophilic Factor [Recombinant])
Company/Manufacturer	Octapharma	Bioverativ	Bayer	CSL Behring	Bayer	Shire	Novo Nordisk	Pfizer	Shire	CSL Behring/ Bayer
Year Approved by FDA	2015	2014	2018	2016	2016	2015	2013	2008	2003	1993
Product Generation*	4th	4th	3rd	3rd	3rd	3rd	3rd	3rd	3rd	2nd
Host Cell Line	Human Embryonic Kidney (HEK)	Human Embryonic Kidney (HEK)	Baby Hamster Kidney (BHK)	Chinese Hamster Ovary (CHO)	Baby Hamster Kidney (BHK)	Chinese Hamster Ovary (CHO)	Chinese Hamster Ovary (CHO)	Chinese Hamster Ovary (CHO)	Chinese Hamster Ovary (CHO)	Baby Hamster Kidney (BHK)
Non-Human Epitopes	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Protein Modification (Peg or Fc Fusion)	No	Yes (Fc fusion)	Yes (PEGylation)	No	No	Yes (PEGylation)	No	No	No	No
FVIII Molecule	B-domain deleted	B-domain deleted	B-domain deleted	B-domain truncated/ Single-chain	Full-length	Full-length	B-domain deleted	B-domain deleted	Full-length	Full-length
Dosage Forms and Strengths (IUs)	250, 500, 1000, 2000, 2500, 3000, 4000	250, 500, 750, 1000, 1500, 2000, 3000, 4000, 5000, 6000	500, 1000, 2000, 3000	250, 500, 1000, 1500, 2000, 2500, 3000	250, 500, 1000, 2000, 3000	250, 500, 750, 1000, 1500, 2000, 3000	250, 500, 1000, 1500, 2000, 3000	250, 500, 1000, 2000, 3000	250, 375, 500, 750, 1000, 1500, 1700, 2000, 2500, 3000, 4000	250, 500, 1000, 2000, 3000
Diluent Volume	2.5 mL	3 mL	2.5 mL	2.5 mL, 5 mL	2.5 mL, 5 mL	2 mL, 5 mL	4 mL	4 mL	2 mL, 5 mL	2.5 mL, 5 mL
Reconstitution Device	Prefilled syringe	Prefilled syringe	Prefilled syringe	Mix2Vial® transfer set	Prefilled syringe	BAXJECT III® system	MixPro™ prefilled syringe	Xyntha Solofuse®	BAXJECT III® system	Mix2Vial®/ BIO-SET®

\*Product generation classification is based on the following criteria: Production in a Hamster or non-Human cell line, use of cell culture media containing human and/or animal proteins, and/or use of human albumin as a stabilizer in the final formulation.

All products shown are indicated in adults and children with Hemophilia A for on-demand treatment and control of bleeding, perioperative management of bleeding, and routine prophylaxis to reduce the frequency of bleeding episodes. Dosing for routine prophylaxis of Xyntha® is not stated in its package insert. Products are not indicated for von Willebrand disease.

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## STORAGE

<b>NUWIQ®</b> Antihemophilic Factor (Recombinant)	Up to 24 months in a refrigerator 2°C to 8°C (35°F to 46°F). Room temperature storage (up to 25°C [77°F]) for a single period not exceeding 3 months. After storage at room temperature, do not return the product to the refrigerator.
<b>ELOCTATE®</b> [Antihemophilic Factor (Recombinant), Fc Fusion Protein]	Store at 2°C to 8°C (36°F to 46°F). Room temperature storage not to exceed 30°C (86°F) for a single period up to 6 months. After storage at room temperature, do not return the product to the refrigerator.
<b>JIVI®</b> [Antihemophilic Factor (Recombinant), PEGylated-aucI]	Up to 24 months in a refrigerator 2°C to 8°C (36°F to 46°F). Room temperature storage (up to 25°C [77°F]) for a single period up to 6 months. Once stored at room temperature, do not return the product to the refrigerator.
<b>AFSTYLA®</b> Antihemophilic Factor (Recombinant), Single Chain	Store at 2°C to 8°C (36°F to 46°F). Do not freeze. Room temperature storage, not to exceed 25°C (77°F), for a single period of up to 3 months, within the expiration date printed on the carton and vial labels. Once stored at room temperature, do not return the product to the refrigerator.
<b>KOVALTRY®</b> [Antihemophilic Factor (Recombinant)]	Store at 2°C to 8°C (36°F to 46°F) for up to 30 months. Do not freeze. Within this period, the product may be stored for a single period of up to 12 months at temperatures up to 25°C or 77°F. Once stored at room temperature, do not return the product to the refrigerator.
<b>ADYNOVATE®</b> [Antihemophilic Factor (Recombinant), PEGylated]	Store at 2°C to 8°C (36°F to 46°F). Room temperature storage not to exceed 30°C (86°F) for a period of up to 3 months. After storage at room temperature, do not return the product to the refrigerator.
<b>NOVOEIGHT®</b> Antihemophilic Factor (Recombinant)	Refrigerate at 2°C to 8°C (36°F to 46°F) for up to 30 months. Within the 30-month period, the product may also be stored at room temperature not to exceed 86°F (30°C) for up to 12 months. Total storage time at room temperature should not exceed 12 months. Do not return the product to the refrigerator.
<b>XYNTHA®</b> Antihemophilic Factor (Recombinant)	Refrigerate at 2°C to 8°C (36°F to 46°F) for up to 36 months. Room temperature storage up to 25°C (77°F) for up to 3 months. At the end of the 3-month period, immediately use or discard the product. Do not put the product back into the refrigerator.
<b>ADVATE®</b> [Antihemophilic Factor (Recombinant)]	Refrigerate at 2°C to 8°C (36°F to 46°F). Room temperature storage up to 30°C (86°F) for a period of up to 6 months. After storage at room temperature, do not return the product back to the refrigerator.
<b>HELIXATE® FS</b> Antihemophilic Factor (Recombinant)  <b>KOGENATE® FS</b> Antihemophilic Factor [Recombinant]	Store at 2°C to 8°C (36°F to 46°F). Room temperature storage (not to exceed 25°C or 77°F) for a period of up to 12 months. After storage at room temperature, do not return the product to the refrigerator.

**IMPORTANT NOTE:** The information provided herein is based on the approved labeling (PI) for each product and is provided for reference only. It is not intended to imply equivalence or claim of superiority between any of the products in terms of safety, efficacy, indications, dosing regimen, tolerability, or any condition of use. It is not intended for use as a guideline for clinical evaluations or choice of product for any individual patient. Such evaluations (including but not limited to initial and/or subsequent dosing or conversions from specific product brands) should utilize a thorough review of appropriate clinical data and consideration of the needs of the individual patient.

Please see accompanying full Prescribing Information or visit [WWW.NUWIQUUSA.com](http://WWW.NUWIQUUSA.com) to view or download a copy.