

Novoeight®— Designed to fit into their lives

A recombinant factor VIII for today's generation of people living with hemophilia A¹

Michael, 30 years old, lives with hemophilia A.

Indications and Usage

Novoeight® (Antihemophilic Factor [Recombinant]) is indicated for use in adults and children with hemophilia A for control and prevention of bleeding, perioperative management, and routine prophylaxis to prevent or reduce the frequency of bleeding episodes.

Novoeight® is not indicated for the treatment of von Willebrand disease.

Important Safety Information

Do not use in patients who have had life-threatening hypersensitivity reactions, including anaphylaxis, to Novoeight® or its components, including hamster proteins.

**Please see additional Important Safety Information throughout and on page 22.
Please see Prescribing Information.**



novoeight®
Antihemophilic Factor
(Recombinant)

Today's patients are looking for a FVIII that fits into their lives

Each phase of life presents new experiences and challenges²⁻⁵



Self-infusing for the first time

Spending the **weekend away** with friends

Going away **on vacation**

Leaving for college

Getting a **job**

Moving in with a significant other

Traveling for business

Living an **active retirement**

Isn't it time to offer the storage flexibility of Novoeight®?



PORTABILITY

- Highest storage temperature for the longest duration—up to 86°F for 12 months^{1,a}
- Longest room temperature storage time after reconstitution—up to 4 hours^{1,a}

^aCompared with other recombinant FVIII products.⁶⁻¹⁴



RELIABILITY

- One of the largest clinical trials of a recombinant FVIII to date showed 0 inhibitors in PTPs¹
- 8 years of clinical experience with Novoeight® in PTPs¹⁵



PURITY

- Extensive 5-step purification process^{16,17}
- Employs state-of-the-art double 20-nm filtration^{17,18}

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Novoeight® is designed for storage flexibility—to fit into their daily lives

The highest storage temperature for the longest time^{1,a}

Before reconstitution

- Novoeight® has room temperature stability for an active lifestyle



^aCompared with other recombinant FVIII products.⁶⁻¹⁴



Longest room temperature storage time after reconstitution^{1,a}

After reconstitution

- Storage of Novoeight® gives patients more time if met with infusion challenges



1 hour longer than most other recombinant factor VIII products⁶⁻¹⁴



of patients and caregivers prefer a FVIII treatment be stored at a higher temperature for longer durations^{19,b}

^b From a Web-based survey of 145 patients and caregivers.

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Novoeight®—offers quick reconstitution and multiple dose strengths

Multiple dose strengths help more patients infuse with fewer vials¹



PREFILLED DILUENT SYRINGE

Contains 4 mL of diluent—works with any dose strength¹



ADAPTER

Connects the syringe and vial, with a 25-µm inline particle filter¹



VIAL WITH COLORED CAP

Easy recognition of different dose strengths by color-coded vial caps¹

250 IU 500 IU 1000 IU 1500 IU 2000 IU 3000 IU

- With MixPro®, preparing a dose of Novoeight® is as quick as ATTACH, TWIST, MIX¹

Important Safety Information (cont'd)

The most frequently reported adverse reactions ($\geq 0.5\%$) were injection site reactions, increased hepatic enzymes, and pyrexia.

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Novoeight® Travel Kit—designed to keep them on the go

SMALL,
CONVENIENT
KIT HOLDS
up to a week's
worth of factor
(3 vials)



Customizable case skins



Compact
packaging for
easy storage

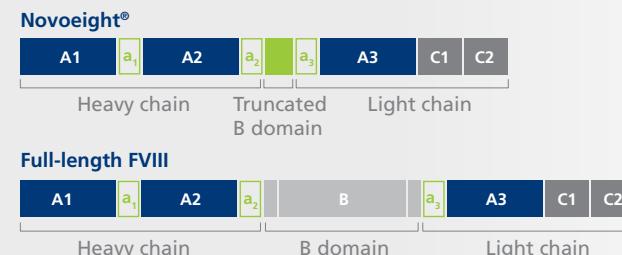
novoeight®
Antihemophilic Factor
(Recombinant)



Novoeight®—designed for reliability with molecular precision

B-domain truncated

Precisely B-domain truncated to achieve a **well-defined product**^{20,21}



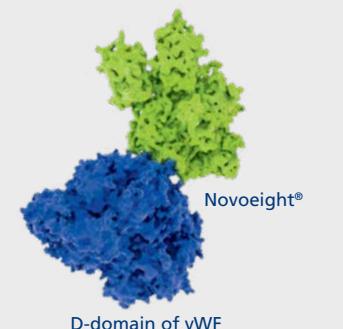
Full Tyr-1680 sulfation

Tyrosine sulfation supports high-affinity binding to vWF^{20-22,b}

- Binding to vWF has been shown to protect FVIII from premature clearance and degradation²⁰⁻²²
- Novoeight® is >99% sulfated at Tyr-1680²³

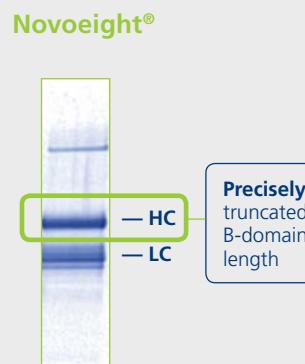
^bThe clinical significance of the degree of tyrosine sulfation has not been established.

vWF=von Willebrand factor.

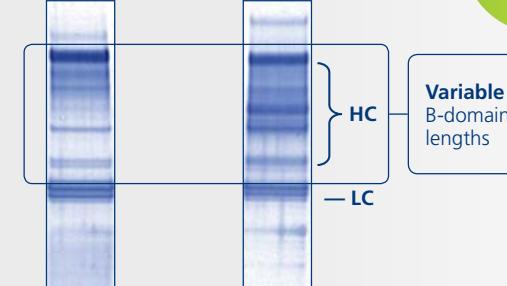


Consistent heavy chain length

FVIII analyzed by SDS-PAGE^{20,a}



Novoeight®
2nd generation (full length)



3rd generation (full length)

Consistent length results in homogeneity^{20,a}

HC
— LC

Immunoaffinity chromatography

- Precise manufacturing process targets and selects molecules with fully intact A2 domains^{21,24}
- Novoeight® is similar to endogenous FVIII in its active form, ensuring effective physiologic activity^{1,21}

A2 domain



SDS-PAGE gel comparison adapted from Thim et al.²¹

HC=heavy chain; LC=light chain; SDS-PAGE=sodium dodecyl sulfate polyacrylamide gel electrophoresis.

^aThis study compared turoctocog alfa with commercially available recombinant FVIII products using SDS-PAGE and Western blotting.²⁰

Consistency from batch to batch—measurable by a standard assay^{25,26}

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Proven reliable in PTPs who switched to Novoeight®

0 inhibitors were confirmed in one
of the largest clinical trials with^{1,a,b}

225
previously
treated patients^{b,c} | **88,000**
infusions

8 years of clinical experience
with Novoeight® in PTPs¹⁵

PTPs=previously treated patients.

^aguardian™1: a multicenter, multinational, open-label, single-arm efficacy and safety trial in 150 patients (aged 12 to 65 years) with severe hemophilia A on a prophylactic treatment regimen who were exposed to turoctocog alfa for a mean of 85 exposure days (ranging from 11 to 172 exposure days).

guardian™3: a multicenter, multinational, noncontrolled, open-label safety, efficacy, and pharmacokinetic trial in 63 previously treated pediatric patients (aged 0 to 11 years) with hemophilia A in which patients were exposed to turoctocog alfa for a mean of 60 exposure days (ranging from 20 to 104 exposure days).^{15,27}

^bguardian™2: a prospective, open-label, uncontrolled extension trial investigating the safety and efficacy of turoctocog alfa in 55 pediatric, 23 adolescent, and 122 adult patients with severe hemophilia A for a mean of 361.6 exposure days. The data cutoff date was December 31, 2013.²⁸

^cPatients with previous inhibitors were excluded from the trials. Individuals with hemophilia A may develop inhibitors to FVIII. Monitor patients taking Novoeight® for inhibitor formation.¹

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Proven effective across age groups

Novoeight® continued to reduce frequency of bleeds, demonstrating effective, long-term prophylaxis²⁸

Median ABR

All patients
(0–65 years old)

3.1

N=213

In initial clinical trials, patients
who took Novoeight® had a
median of 3.1 bleeds per year.¹

Children
(≤11 years old)

3.0

N=63

In an initial clinical trial, children
who took Novoeight® had a median
of 3.0 bleeds per year.²⁷

Safety extension trial

1.6

N=197

The majority of patients continued in a safety extension
trial. Results from an interim analysis showed that
patients had a median of 1.6 bleeds per year.²⁸

ABR=annualized bleed rate.

novoeight®
Antihemophilic Factor
(Recombinant)



RELIABILITY

Long-term use of Novoeight®—effective in prevention and treatment of bleeds

89%

of all bleeds (traumatic and spontaneous) were mild to moderate²⁸

- The majority of bleeding episodes for children treated with Novoeight® were caused by traumatic injury²⁸

guardian™2: a prospective, open-label, uncontrolled extension trial investigating the safety and efficacy of turoctocog alfa in 55 pediatric, 23 adolescent, and 122 adult patients with severe hemophilia A for a mean of 361.6 exposure days. The data cutoff date was December 31, 2013.²⁸



Oscar, 8 years old, lives with hemophilia A.

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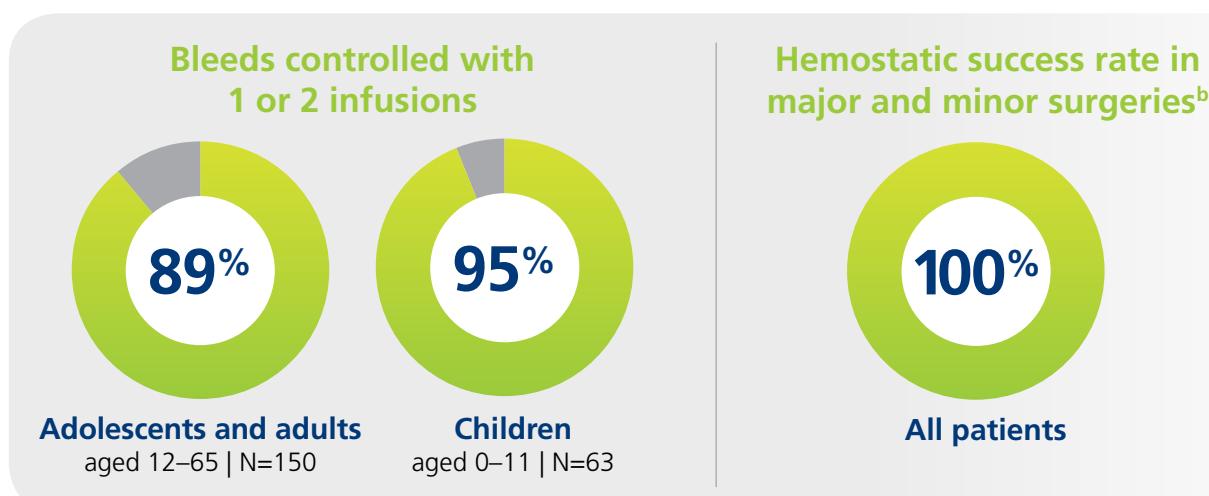
Sion, 11 years old, lives with hemophilia A.

novoeight®
Antihemophilic Factor
(Recombinant)



Novoeight®—proven reliability in the treatment of bleeds

Results from guardian™1 and guardian™3 pivotal trials^{15,27,29,a}



^aguardian™1: a multicenter, multinational, open-label, single-arm efficacy and safety trial in 150 patients (aged 12 to 65 years) with severe hemophilia A on a prophylactic treatment regimen who were exposed to turoctocog alfa for a mean of 85 exposure days (ranging from 11 to 172 exposure days).¹⁵

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^bA hemostatic response rated as "excellent" or "good" was considered treatment success. If hemostatic response was rated as "moderate" or "none," the treatment was considered treatment failure. Missing data were included in the treatment failure category.²⁹

Established safety profile of Novoeight®

Novoeight® was shown to be safe and effective in pivotal trials^{1,15,27}

- Safety results consistent among adults, adolescents, and children¹
- No thromboembolic events occurred during the trials^{28,29}
- The most frequently reported adverse reactions in previously treated patients were injection site reactions (2.3%), increased hepatic enzymes (1.4%),^c and pyrexia (0.9%)¹



Alberto, 37 years old, lives with hemophilia A.

^cAll patients who reported increased hepatic enzymes had hepatitis C at screening.¹⁵

Important Safety Information (cont'd)

The most frequently reported adverse reactions ($\geq 0.5\%$) were injection site reactions, increased hepatic enzymes, and pyrexia.

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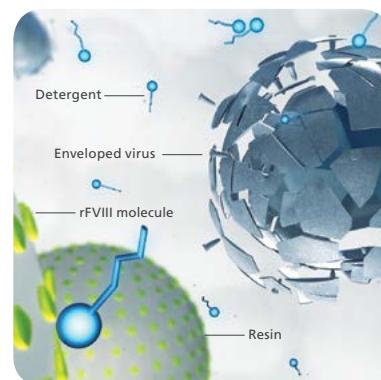
Novoeight®—designed with purity in mind

Our rigorous five-step purification process minimizes the risk of viral and protein contamination^{16,17}

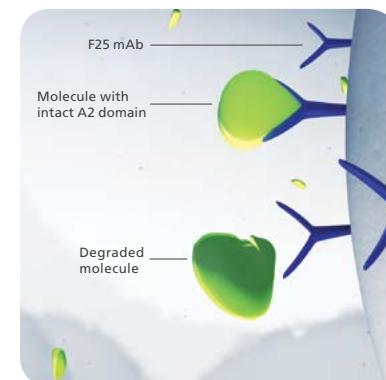
Extensive
5-step
purification
process^{16,17}

1**DETERGENT INACTIVATION**

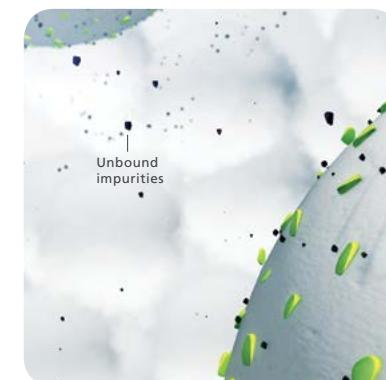
Manufactured without the addition of any human- or animal-derived protein in the cell culture process, purification, or final formulation.^{1,30,a}



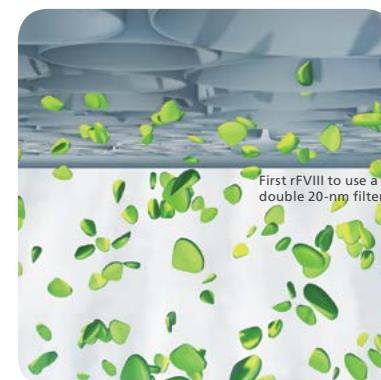
Helps eliminate enveloped viruses

2**IMMUNOAFFINITY CHROMATOGRAPHY**

Uniquely selects intact molecules

3**ANION-EXCHANGE CHROMATOGRAPHY**

Separates molecules from impurities, based on their charge

4**DOUBLE NANOFILTRATION**

Removes small pathogens, reducing non-enveloped viruses

5**GEL FILTRATION**

Reduces FVIII multimers

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A continuing commitment to the community



ONGOING
FOCUS

At Novo Nordisk® we believe that the formula for lasting success is to stay focused, think long-term, and do business in a financially, socially, and environmentally responsible way.



PRODUCT
PORTFOLIO

We are committed to helping patients with treatments for:

- FVII deficiency
- FVIII deficiency
- FVIII deficiency with inhibitors
- FIX deficiency with inhibitors
- FXIII deficiency
- Glanzmann's thrombasthenia
- Acquired hemophilia



ENVIRONMENTAL
AWARENESS

We not only aspire to be a respected leader in the healthcare industry, we continuously strive to minimize the environmental impact of our activities. Our facilities in Denmark supply quality products in a socially responsible and environmentally sound way, using 100% renewable energy.³¹



NovoSecure™ gives your patients the support they need



QuickCheck™ checks if your patients are covered in 4 hours or less^a

FAST BENEFITS VERIFICATION

- QuickCheck™ provides a summary of coverage
- Offers alternative therapies if Novo Nordisk Inc. product is not covered



COMPREHENSIVE CASE MANAGEMENT

- Prior authorization
- Appeals support
- Specialty pharmacy verification



SUPPORT

- NovoSecure™ Welcome Kit
- Product support
- Patient reauthorization
- Ongoing case management
- Additional resources and communications

Free trial^a—for up to 6 doses
Product assistance^a—for up to 12 months
Co-pay assistance^a—for up to \$12,000 annually on co-pay, deductible, and coinsurance costs, regardless of income
Interim Product^a—for up to 12 months



**TO LEARN MORE ABOUT THESE AND OTHER SUPPORT RESOURCES
VISIT MyNovoSecure.com OR CALL (1-844-668-6732).**

- NovoSecure™ also has representatives that speak Spanish to better serve your patients

^aEligibility restrictions apply. Patients participating in any government, state, or federally funded medical or prescription benefit programs, including Medicare, Medicaid, Medigap, VA, DOD, and TRICARE, are not eligible to participate. Please contact NovoSecure™ for complete eligibility requirements for each of the product support offerings.

QuickCheck™ will tell you if Novo Nordisk treatment is covered by your patient's insurance. If it is not covered, QuickCheck™ will provide a preliminary summary of alternate therapies that are covered by your patient's insurance. Available from 9:00 am to 4:00 pm ET.



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The most frequently reported adverse reactions ($\geq 0.5\%$) were injection site reactions, increased hepatic enzymes, and pyrexia.

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32. Data on file. Novo Nordisk Inc; Plainsboro, NJ.



^aRecombinant factor VIII.

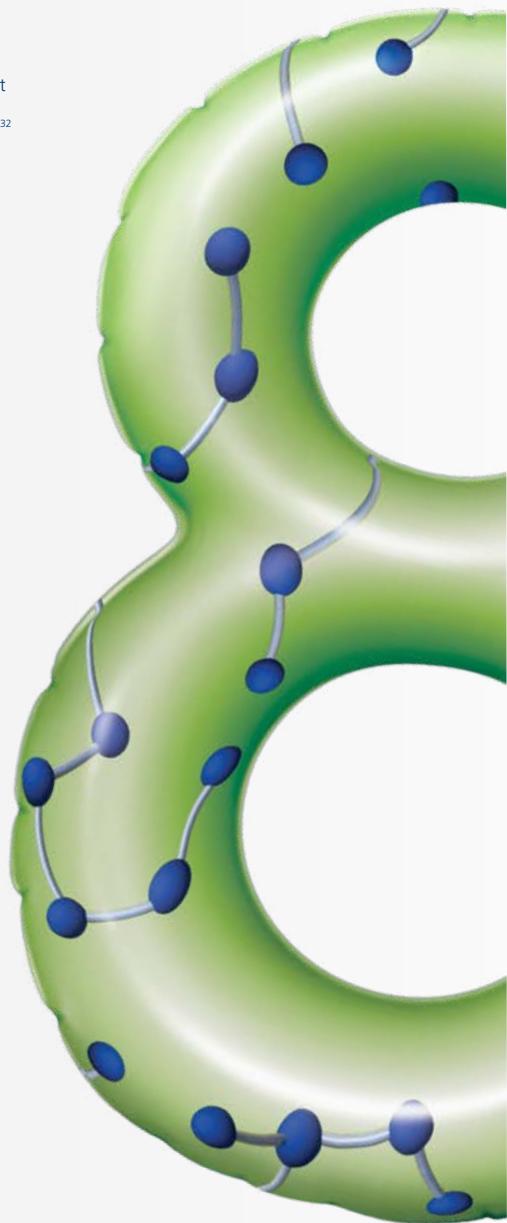
^bBased on data for Q2 2015-Q1 2016; accounts for net gains and losses of patients switching to and from standard half-life rFVIII available for at least one year.³²

For today's generation of people
living with hemophilia

Novoeight® is designed to fit into their lives

- Learn how Novoeight® provides your patients storage flexibility they need in their treatment
- Discover Novo Nordisk's continued commitment to helping patients with rare bleeding disorders
- Find out about the support offered by Novo Nordisk

Visit Novoeightpro.com today to learn more.



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