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Introducing a **NEW** recombinant factor VIII for  
the treatment of haemophilia A<sup>1</sup>

# NovoEight<sup>®</sup> is designed to fit into his world



*Julian, 25 years old, is  
studying for a career in social  
work and enjoys working with  
children as a camp counsellor.  
Julian lives with haemophilia A.*



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# Entering **new phases** of life can bring challenges that may affect his FVIII treatment<sup>2,3</sup>

- Dealing with a chronic disease<sup>2</sup>
- Becoming one's own caregiver<sup>2</sup>
- Achieving independence<sup>2</sup>

Phases of transition<sup>2,3</sup>



Building  
relationships



# Entering **new phases** of life can bring challenges that may affect his FVIII treatment<sup>2,3</sup>

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## Phases of transition<sup>2,3</sup>





# His changing world demands a FVIII that **supports** him

NovoEight®, the **first new rFVIII** molecule in over a decade,<sup>1,4-9</sup> is deliberately designed for:

## RELIABILITY

to support his health

## PURITY AND SAFETY

to give him peace of mind

## PORTABILITY

to support his independence





# His changing world demands a FVIII that **supports** him

NovoEight®, the **first new rFVIII** molecule in over a decade,<sup>1,4-9</sup> is deliberately designed for:

## RELIABILITY<sup>1</sup>

PTPs who switched to NovoEight®  
in pivotal trials developed

**0** INHIBITORS\*

- Consistent activity from batch to batch<sup>1,10</sup>
- Efficacy proven in the largest pivotal trial programme of any approved rFVIII (N=213)<sup>1,11</sup>

## PURITY AND SAFETY<sup>12-14</sup>

First rFVIII to use a

**20** NM FILTER

- Five-step purification process including unique immunoaffinity chromatography and nanofiltration<sup>4,12</sup>
- Well tolerated in clinical trials<sup>1,15,16</sup>

## PORTABILITY<sup>1,17-19</sup>

The only rFVIII with storage at

**30°** CELSIUS

- Enhanced room temperature stability<sup>1</sup>

PTP=previously treated patient.

\*Patients with previous inhibitors were excluded from the trials. Individuals with haemophilia A may develop inhibitors to FVIII. Monitor patients taking NovoEight® for inhibitor formation.<sup>1,20</sup>



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# His changing world demands a FVIII that **supports** him

Patients entering new phases of life  
require support and stability<sup>2,3,21</sup>

**RELIABILITY<sup>1</sup>**  
to support his health

**PURITY AND SAFETY<sup>12-14</sup>**  
to give him peace of mind

**PORTABILITY<sup>1</sup>**  
to support his independence



*Lino, 27 years old; Lawrence, 19 years old; Blerim, 24 years old;  
Michel, 30 years old; and Julian, 25 years old. They live with haemophilia A.*



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# Entering **new phases** of life can bring challenges that may affect his FVIII treatment<sup>2,3</sup>

- Dealing with a chronic disease<sup>2</sup>
- Becoming one's own caregiver<sup>2</sup>
- Achieving independence<sup>2</sup>

Phases of transition<sup>2,3</sup>



Building  
relationships



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# Entering **new phases** of life can bring challenges that may affect his FVIII treatment<sup>2,3</sup>

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Phases of transition<sup>2,3</sup>



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# Entering **new phases** of life can bring challenges that may affect his FVIII treatment<sup>2,3</sup>

- Dealing with a chronic disease<sup>2</sup>
- Becoming one's own caregiver<sup>2</sup>
- Achieving independence<sup>2</sup>

Patients in transition require support and stability<sup>2,3,21</sup>

**RELIABILITY<sup>1</sup>**  
to support his health

**PURITY AND SAFETY<sup>10-12</sup>**  
to give him peace of mind

**PORTABILITY<sup>1</sup>**  
to support his independence



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# NovoEight® is deliberately designed for **reliability**

- Consistent activity from batch to batch<sup>1,10</sup>
- Efficacy proven in the largest pivotal trial programme of any approved rFVIII (N=213)<sup>1,11</sup>

PTPs who switched to NovoEight®  
in pivotal trials developed

**0** INHIBITORS<sup>1\*</sup>

PTP=previously treated patient.

\*Patients with previous inhibitors were excluded from the trials. Individuals with haemophilia A may develop inhibitors to FVIII. Monitor patients taking NovoEight® for inhibitor formation.<sup>1,20</sup>



**Michel, 30 years old,** works as a purchaser and loves to ride his motorbike. Michel lives with haemophilia A.



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# The performance of NovoEight® was proven in the **largest pivotal trial programme** of any approved rFVIII<sup>1,11</sup>

The guardian™1 and guardian™3 clinical trials studied performance in **213 PTPs**<sup>1,11\*</sup>

Overview of rFVIII pivotal trials in PTPs <sup>1,11,17,21–23†</sup>		
rFVIII	Number of patients	Number of inhibitors
NovoEight®	<b>213</b>	<b>0</b>
Second-generation full-length	<b>73</b>	<b>0</b>
Third-generation full-length	<b>108</b>	<b>1</b>
Third-generation B-domain deleted	<b>204</b>	<b>3</b>

PTP=previously treated patient.

\*The studies included 213 exposed patients with severe haemophilia A defined as FVIII activity  $\leq 1\%$ ; 150 adolescent or adult patients without inhibitors  $\geq 12$  years of age ( $\geq 150$  exposure days) received 20–40 IU/kg of NovoEight® every second day or 20–50 IU/kg three times weekly; 63 paediatric patients without inhibitors  $< 12$  years of age ( $\geq 50$  exposure days) received 25–50 IU/kg of NovoEight® every second day or 25–60 IU/kg three times weekly.<sup>1,20</sup>

†Not head-to-head trials. All trials required  $\geq 50$  exposure days and excluded patients with a history of inhibitors ( $> 0.6$  BU or  $> 1.0$  BU). This table is not intended to imply a benefit in terms of efficacy or safety for any one product. Trials cannot be directly compared due to different design, duration, study population, inhibitor testing frequency and other parameters.<sup>1,11,20</sup>



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# The performance of NovoEight® was proven in the **largest pivotal trial programme** of any approved rFVIII<sup>1,11</sup>

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Third-generation full-length	<b>108</b>	<b>1</b>
Third-generation B-domain deleted	<b>204</b>	<b>3</b>

**0** INHIBITORS detected in all PTPs who switched to NovoEight® in pivotal trials<sup>‡</sup>

<sup>‡</sup>Patients with previous inhibitors were excluded from the trials. Individuals with haemophilia A may develop inhibitors to FVIII. Monitor patients taking NovoEight® for inhibitor formation.<sup>1,20</sup>  
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<sup>†</sup>Not head-to-head trials. All trials required ≥50 exposure days and excluded patients with a history of inhibitors (>0.6 BU or >1.0 BU). This table is not intended to imply a benefit in terms of efficacy or safety for any one product. Trials cannot be directly compared due to different design, duration, study population, inhibitor testing frequency and other parameters.<sup>1,11,20</sup>



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# NovoEight® delivered **consistent performance** in adults, adolescents and children<sup>15,16,20</sup>

## Results from guardian™1 and guardian™3<sup>15,16,20</sup>

**guardian™1**  
Adolescents & adults  
aged 12–65 | N=150

**guardian™3**  
Children  
aged 0–11 | N=63

**Haemostatic success rate\***

**Bleeds resolved with  
1–2 injections**

\*Haemostatic response rated as “excellent” or “good” was considered treatment success. If haemostatic response was rated as “moderate” or “none,” the treatment was counted as a failure. Missing data were included in the treatment failure category.



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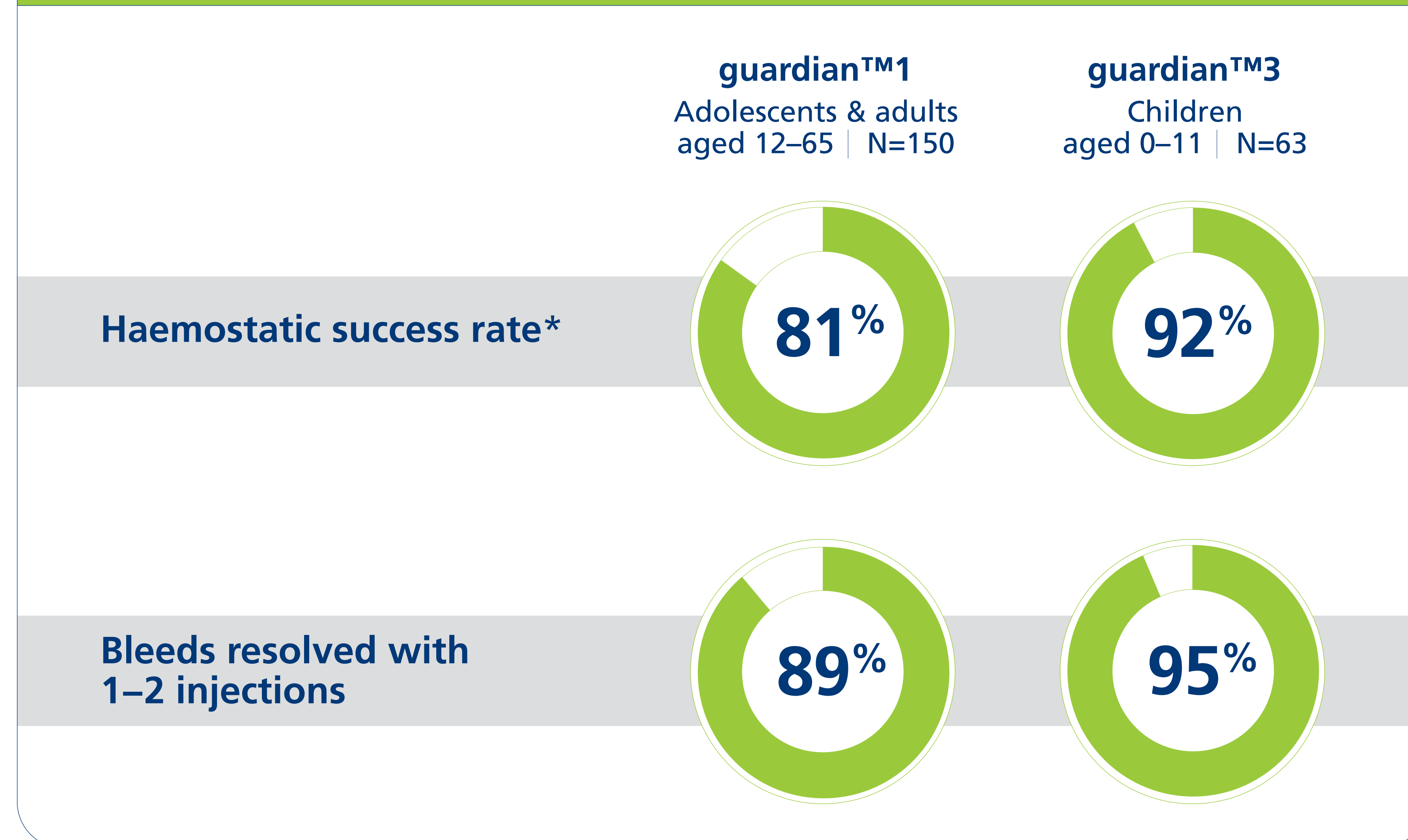
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# NovoEight® delivered **consistent performance** in adults, adolescents and children<sup>15,16,20</sup>

## Results from guardian™1 and guardian™3<sup>15,16,20</sup>



**100% haemostatic success rate** in major and minor surgeries in adolescents and adults<sup>1</sup>

\*Haemostatic response rated as “excellent” or “good” was considered treatment success. If haemostatic response was rated as “moderate” or “none,” the treatment was counted as a failure. Missing data were included in the treatment failure category.



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# NovoEight® is the **first new molecule** in over a decade<sup>1,4-9</sup>



**Today**  
NovoEight®:  
1<sup>st</sup> fully tyrosine  
sulphated rFVIII<sup>4,25</sup>



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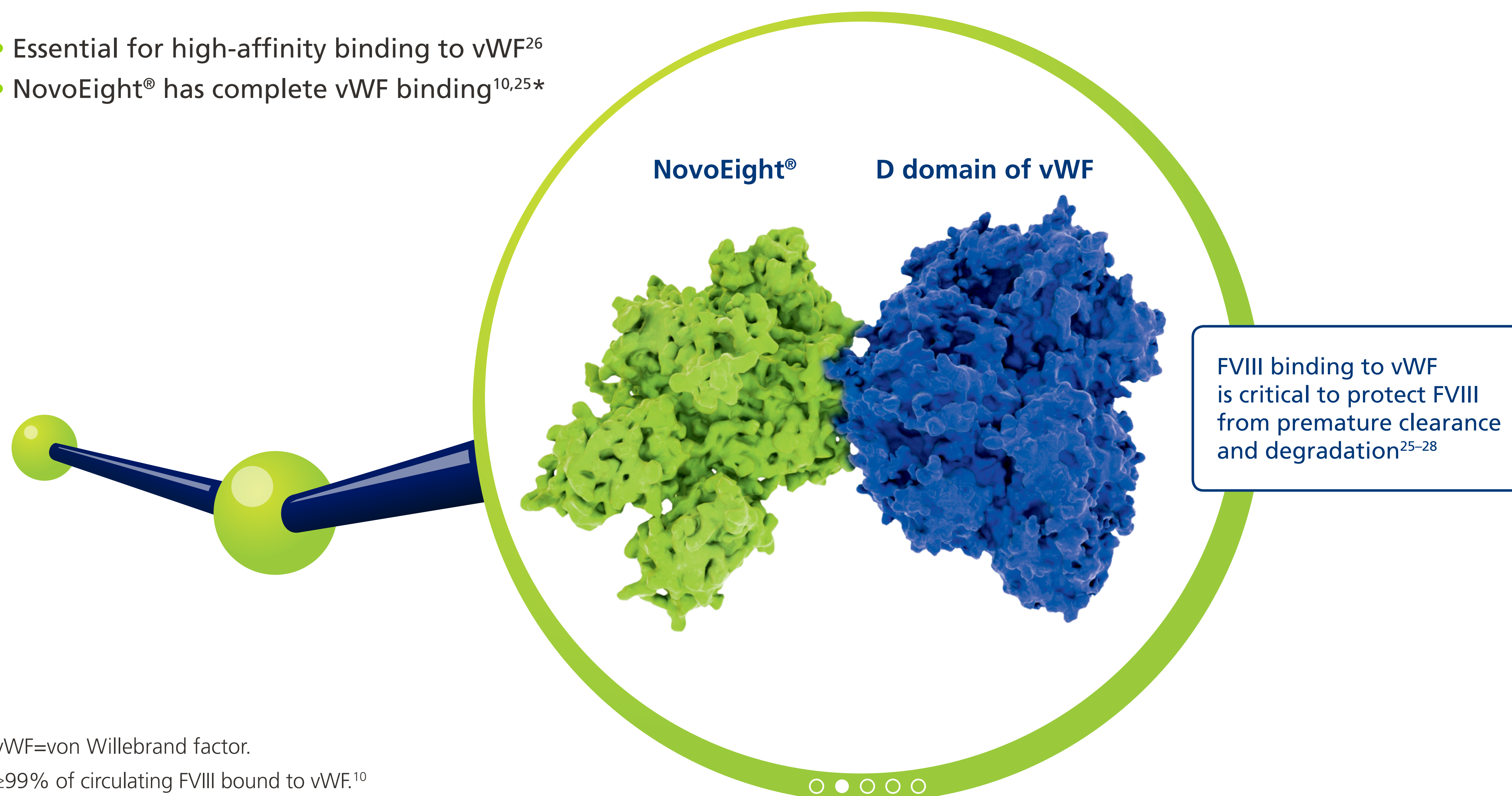
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# NovoEight® is the only approved rFVIII with **full tyrosine sulphation** at Tyr-1680<sup>1,4,25</sup>

- Essential for high-affinity binding to vWF<sup>26</sup>
- NovoEight® has complete vWF binding<sup>10,25\*</sup>

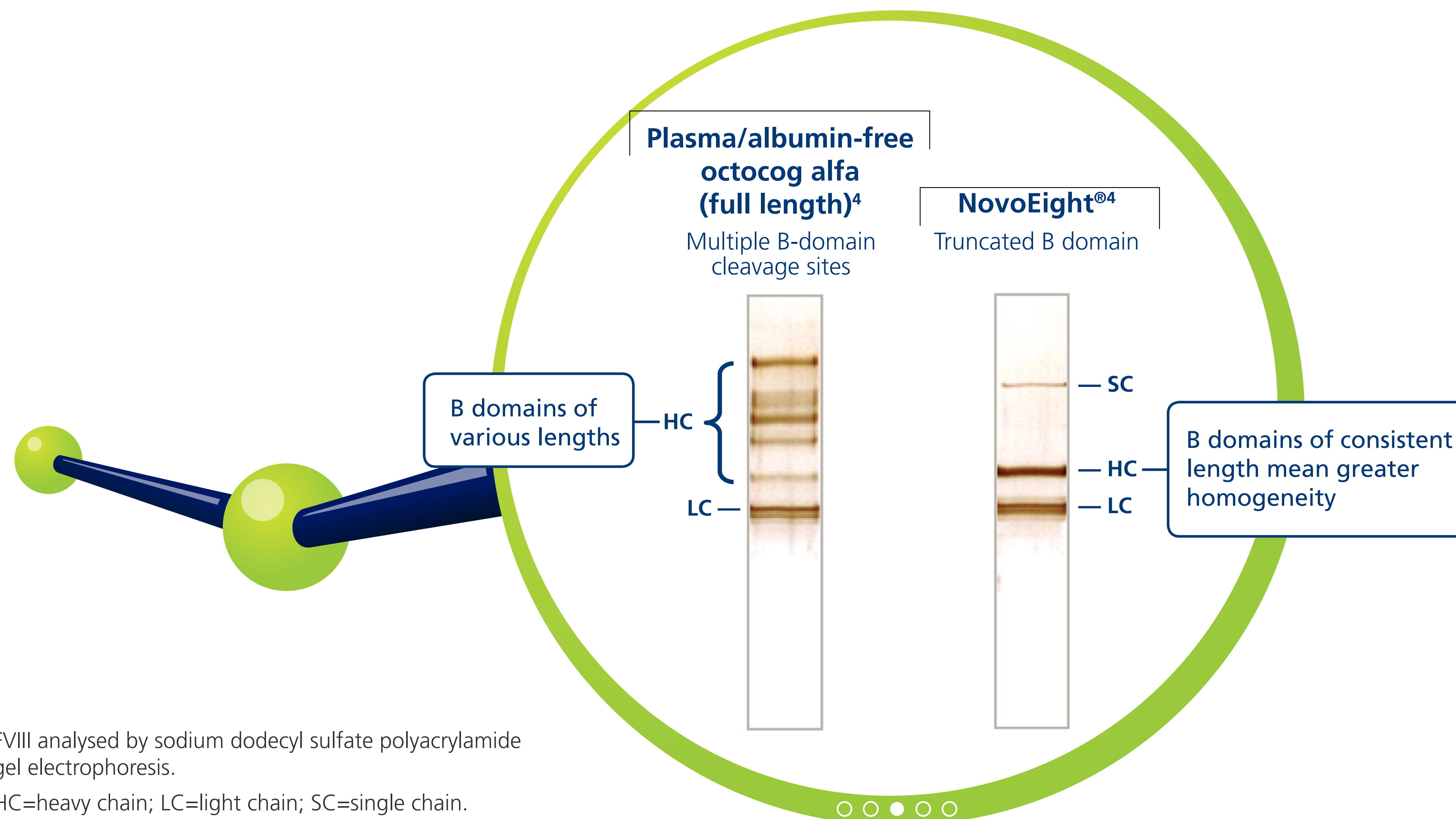
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# NovoEight® is B-domain truncated for a **homogeneous product**<sup>1,4</sup>

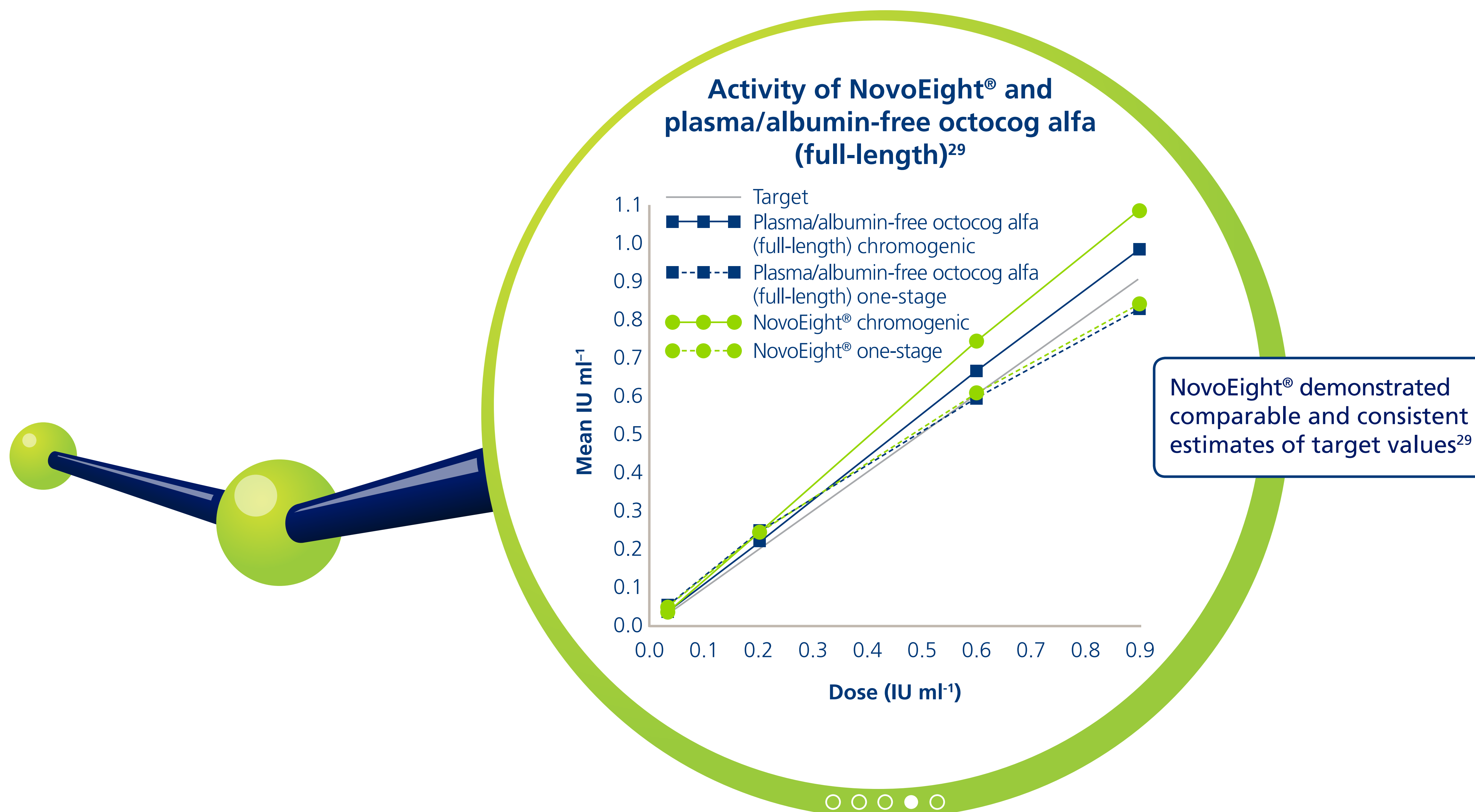
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# NovoEight® can be measured reliably using standard assays<sup>29</sup>



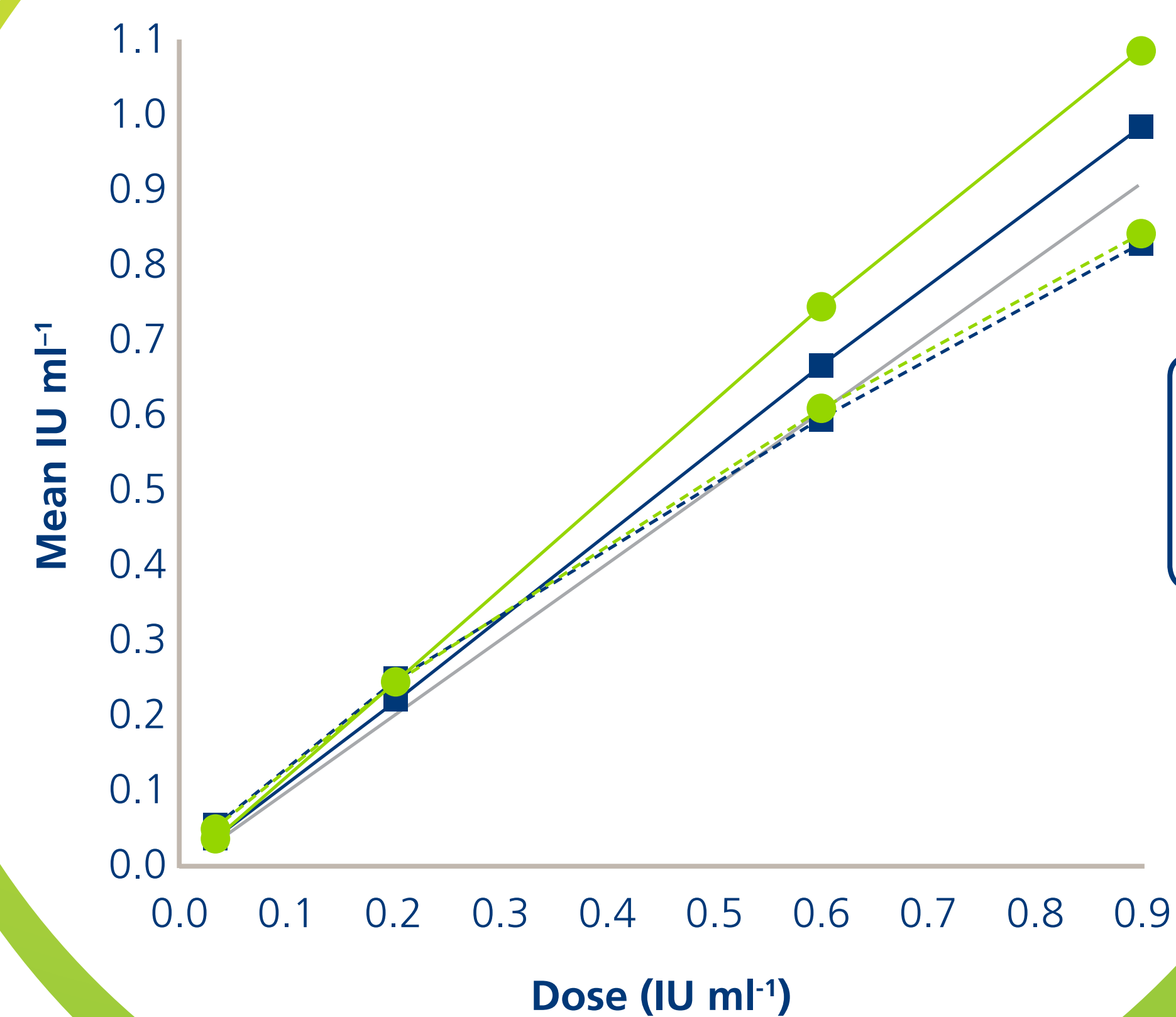


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# NovoEight® can be reliably measured using standard assays

- Target
- Plasma/albumin-free octocog alfa (full-length) chromogenic
- Plasma/albumin-free octocog alfa (full-length) one-stage
- NovoEight® chromogenic
- NovoEight® one-stage

Activity of NovoEight® and plasma/albumin-free octocog alfa (full-length)



NovoEight® demonstrated comparable and consistent estimates of target values<sup>29</sup>

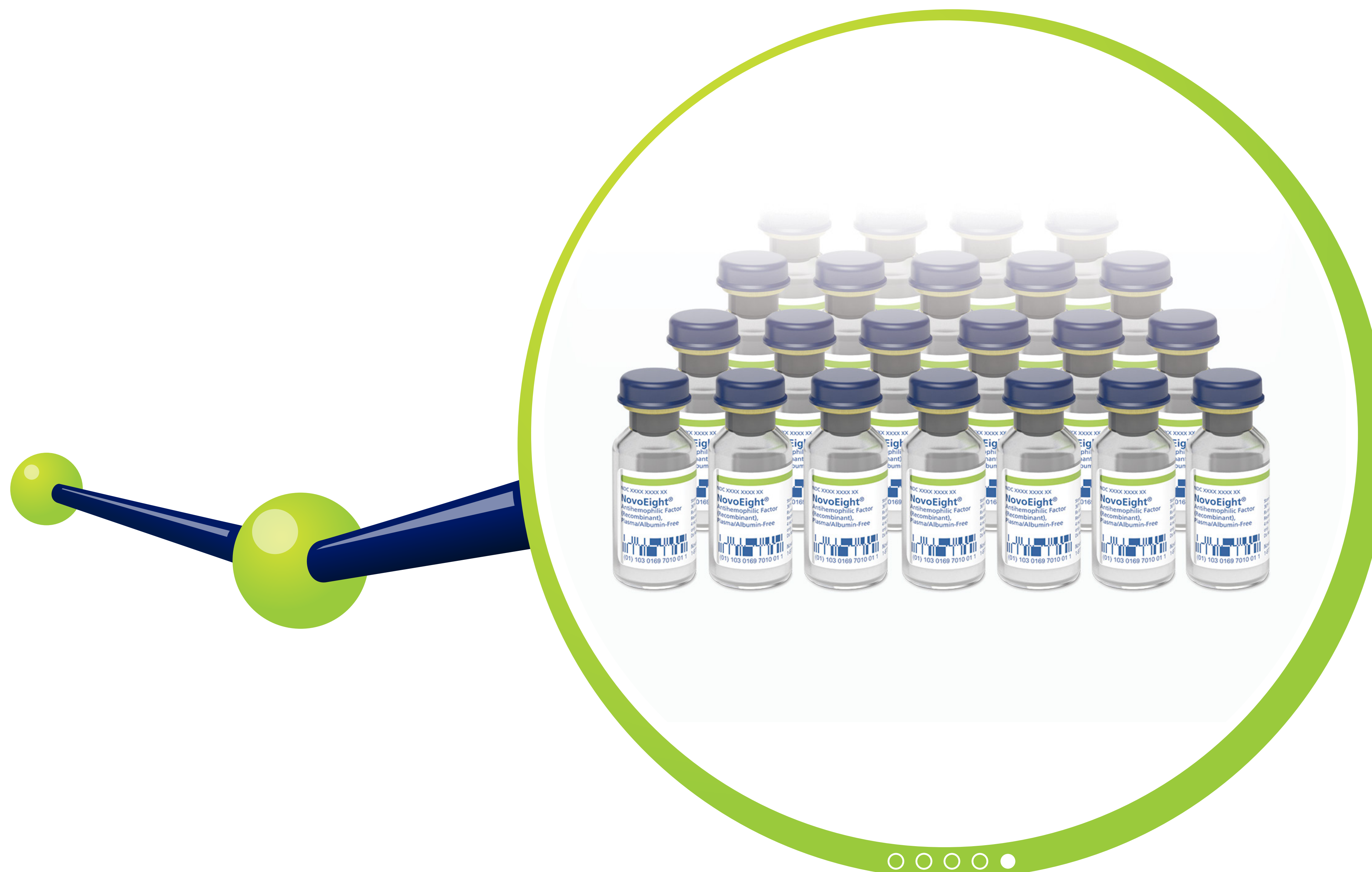
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# NovoEight® demonstrated **consistent activity** from batch to batch<sup>1,10</sup>

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# NovoEight® is designed to take **purity** and **safety** a step forward

- Five-step purification process including unique immunoaffinity chromatography and nanofiltration<sup>4,12</sup>
- Well tolerated in clinical trials<sup>1,15,16</sup>

First rFVIII to use a

**20** NM FILTER<sup>12-14</sup>



***Lino, 27 years old,** works as a social security specialist and travels every weekend to play clarinet in the orchestra. Lino lives with haemophilia A.*



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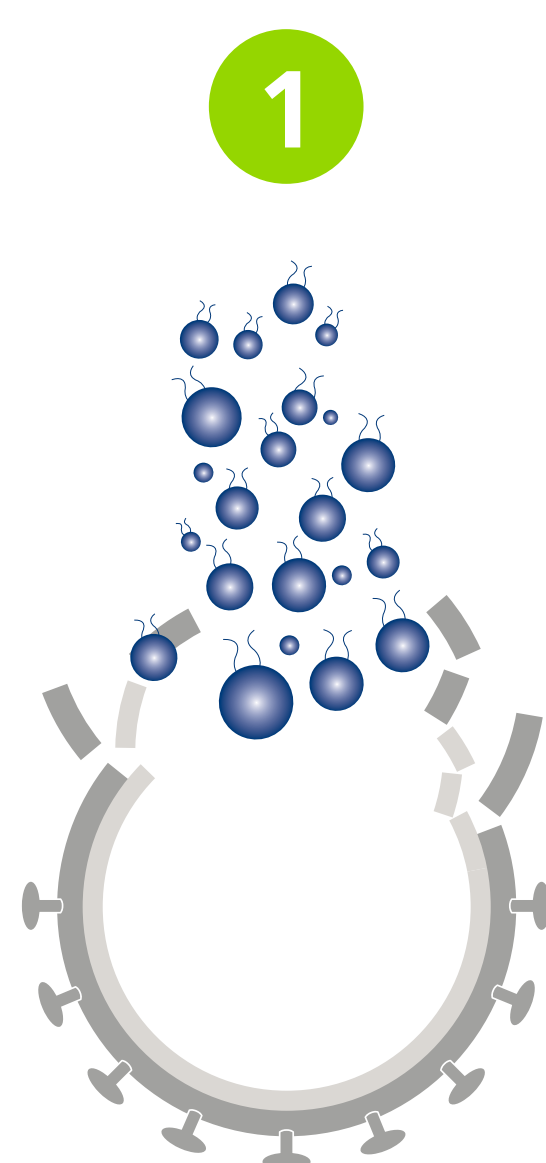


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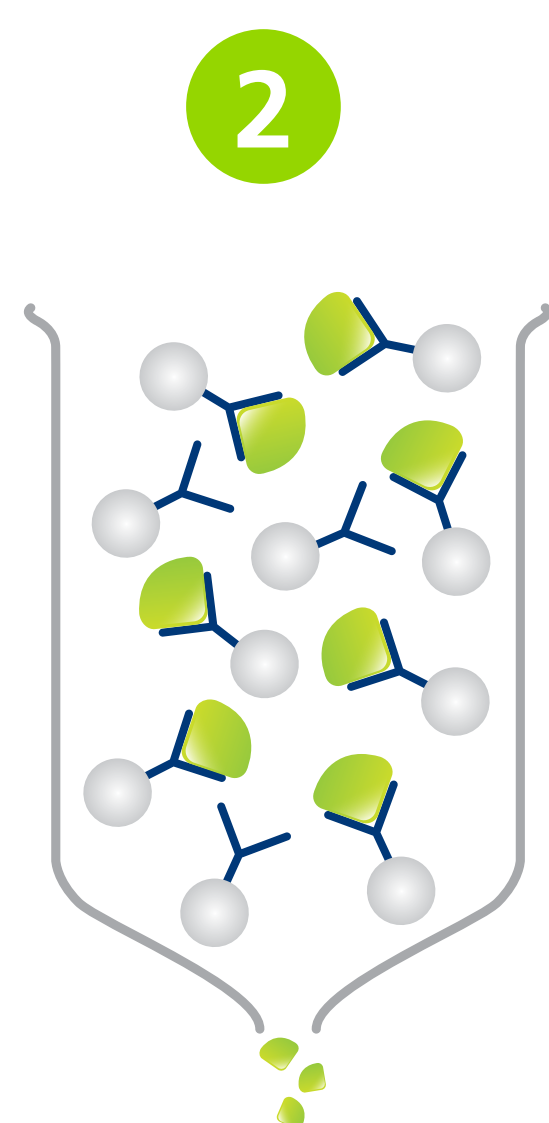
# NovoEight® is the first rFVIII to use a 20-nm filter<sup>12-14</sup>

- No animal- or human-derived components used in the production of NovoEight®<sup>1,4</sup>

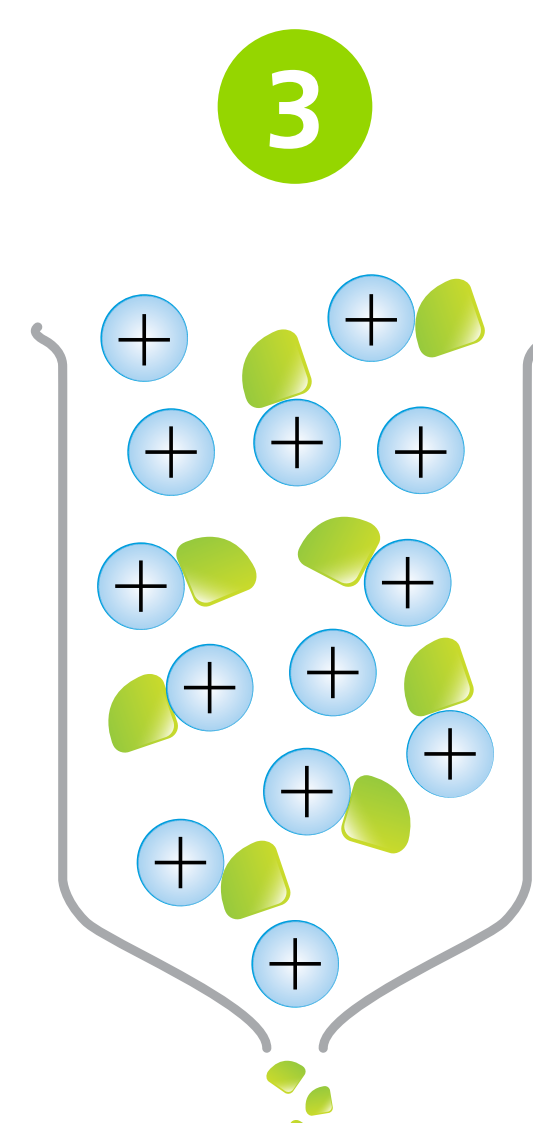
The **NovoEight® purification** process<sup>4,12</sup>



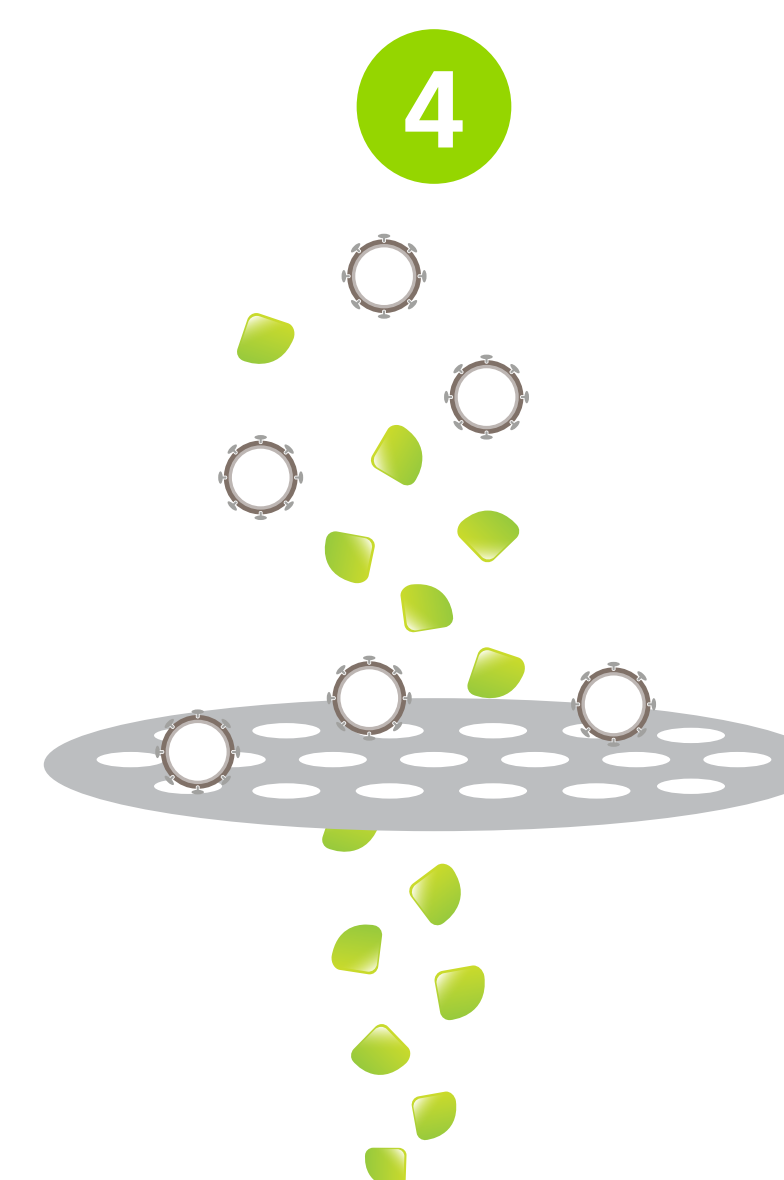
**Detergent inactivation**  
Helps eliminate enveloped viruses



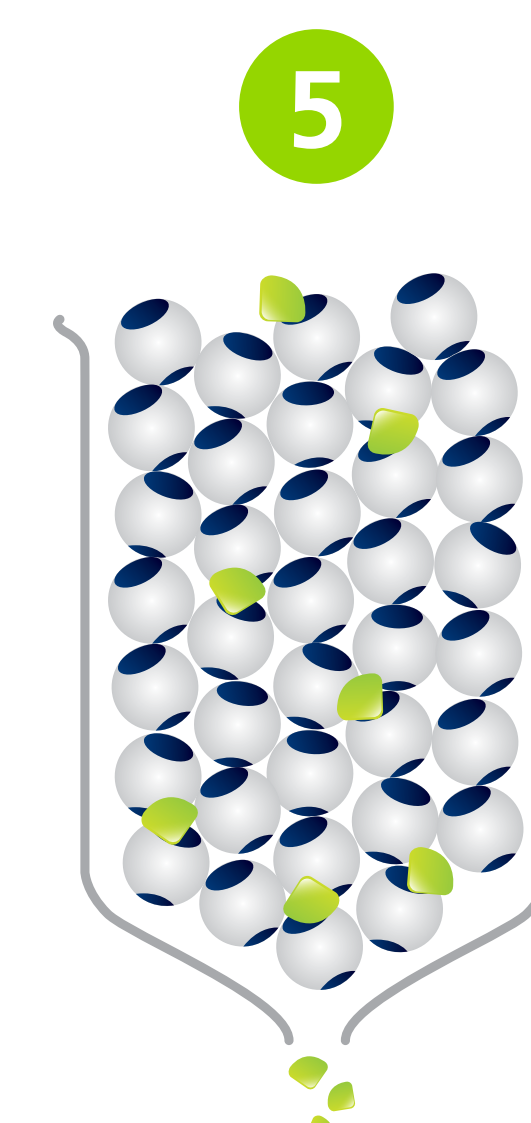
**Immunoaffinity chromatography**  
mAb uniquely selects intact molecules



**Anion-exchange chromatography**  
Separates molecules by their charge



**Nanofiltration**  
20-nm filter has been shown to remove small pathogens, reducing non-enveloped viruses (eg, B19) and prions<sup>12,13</sup>



**Gel filtration**  
Removes FVIII multimers

mAb=monoclonal antibody.



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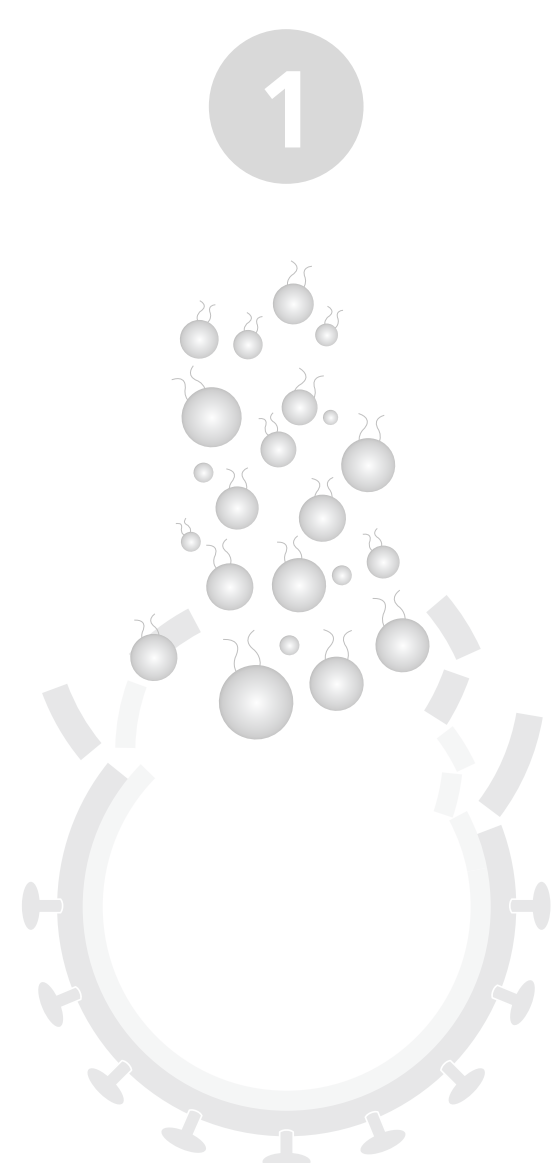


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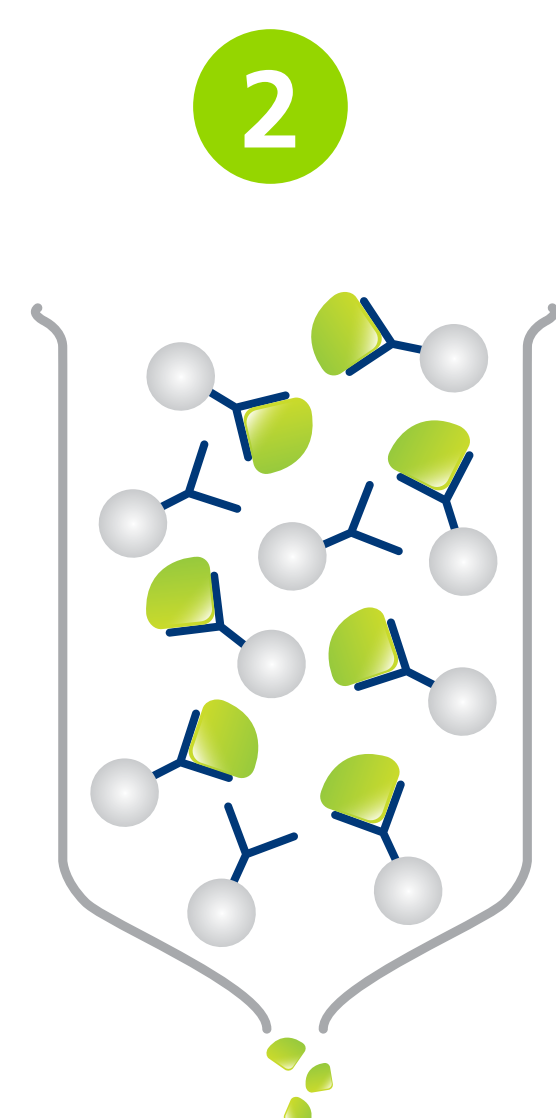
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The **NovoEight® purification** process<sup>4,12</sup>

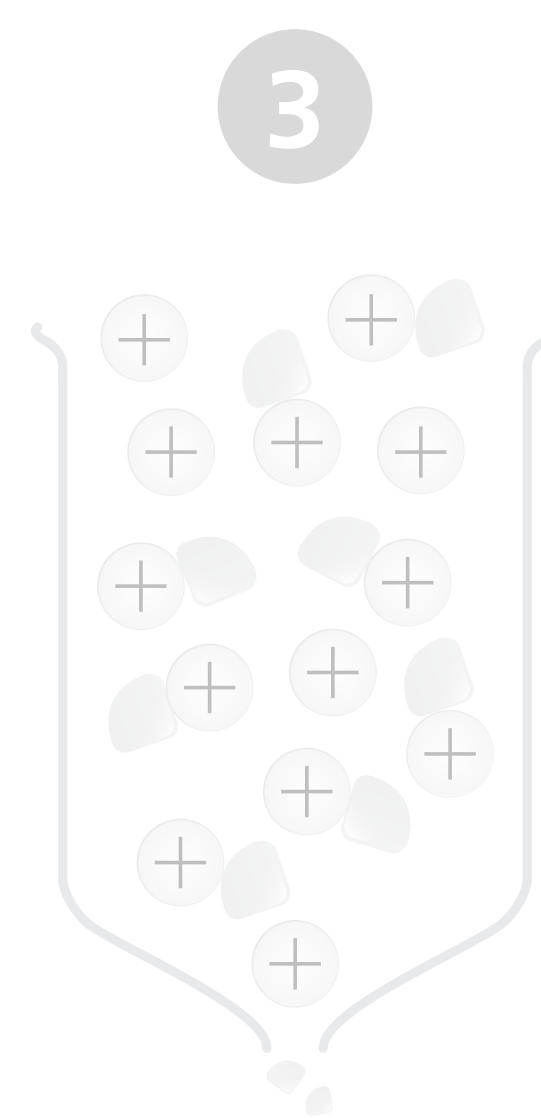


**Detergent inactivation**  
Helps eliminate  
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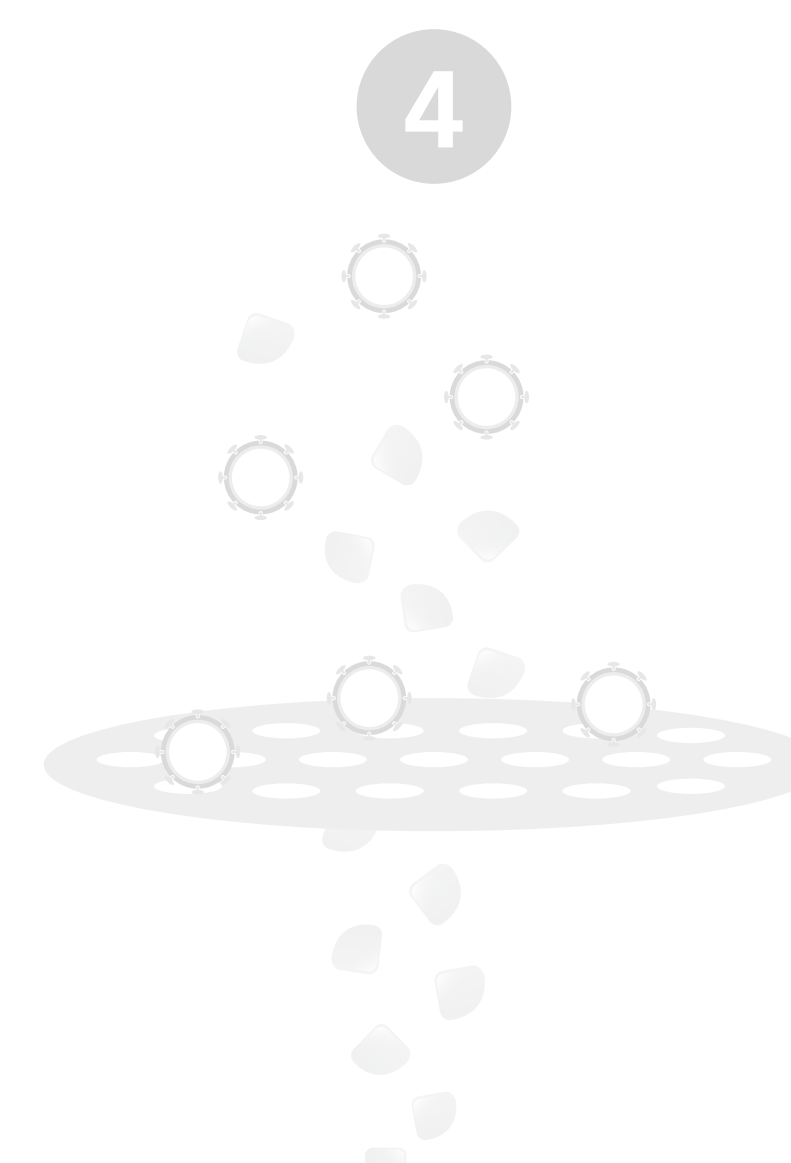


**Immunoaffinity chromatography**  
mAb uniquely selects  
intact molecules

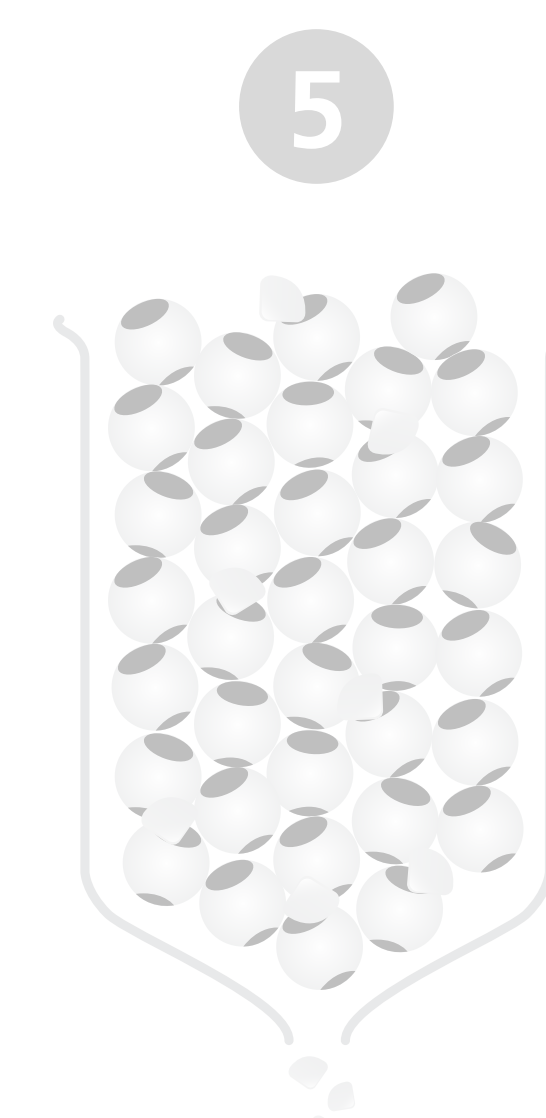
mAb is manufactured in  
a CHO cell line to avoid  
adding potential antigens



**Anion-exchange chromatography**  
Separates molecules  
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**Nanofiltration**  
20-nm filter has been shown  
to remove small pathogens,  
reducing non-enveloped  
viruses (eg, B19) and prions<sup>12,13</sup>



**Gel filtration**  
Removes FVIII  
multimers

mAb=monoclonal antibody;  
CHO=Chinese hamster ovary.



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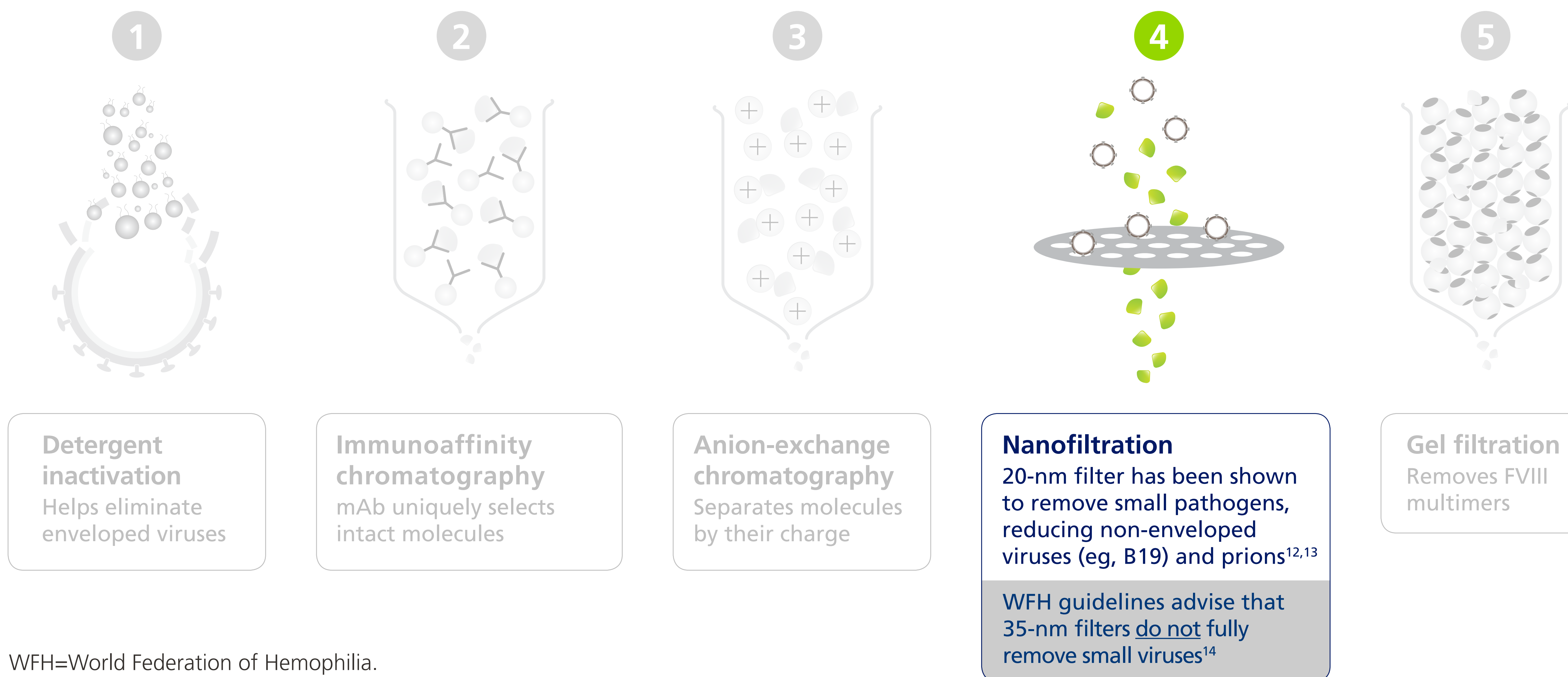


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# ~~NovoEight~~<sup>®</sup> is the first rFVIII to use a **20-nm filter**<sup>12-14</sup>

- No animal- or human-derived components used in the production of NovoEight<sup>®1,4</sup>

The **NovoEight<sup>®</sup> purification** process<sup>4,12</sup>



WFH=World Federation of Hemophilia.



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# NovoEight<sup>®</sup> was **well tolerated** across guardian<sup>™</sup>1 and guardian<sup>™</sup>3<sup>1,20</sup>

## Frequency of adverse drug reactions across guardian<sup>™</sup>1 and guardian<sup>™</sup>3<sup>1</sup>

Adverse reaction	Frequency* <sup>†</sup>
Hepatic enzymes increased <sup>‡</sup>	<10%
Injection site reactions <sup>§</sup>	<10%
Insomnia	<1%
Headache, dizziness	<1%
Sinus tachycardia	<1%
Hypertension, lymphoedema	<1%
Rash	<1%
Musculoskeletal stiffness, arthropathy, pain in extremity, musculoskeletal pain	<1%
Fatigue, feeling hot, oedema peripheral, pyrexia	<1%
Heart rate increased	<1%
Contusion	<1%

- Adverse events reported in 9% of patients<sup>1\*</sup>
- Safety results consistent among children, adolescents and adults<sup>1</sup>
- No thromboembolic events occurred during the trials<sup>20</sup>

\*Calculated based on total number of unique patients in all clinical studies: N=214.

<sup>†</sup>Frequencies have been evaluated according to the following convention: common ( $\geq 1/100$  to  $< 1/10$ ), uncommon ( $\geq 1/1,000$  to  $< 1/100$ ).

<sup>‡</sup>Hepatic enzymes increased include alanine aminotransferase, aspartate aminotransferase, gamma-glutamyltransferase and bilirubin.

<sup>§</sup>Injection site reactions include injection site erythema, injection site extravasation and injection site pruritus.



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# NovoEight® is designed for portability that supports his independence

- Enhanced room temperature stability<sup>1</sup>

The only rFVIII with storage at

**30°** CELSIUS<sup>1,17-19</sup>



**Blerim, 24 years old,** works in an office as a commercial trainee and enjoys travelling. Blerim lives with haemophilia A.



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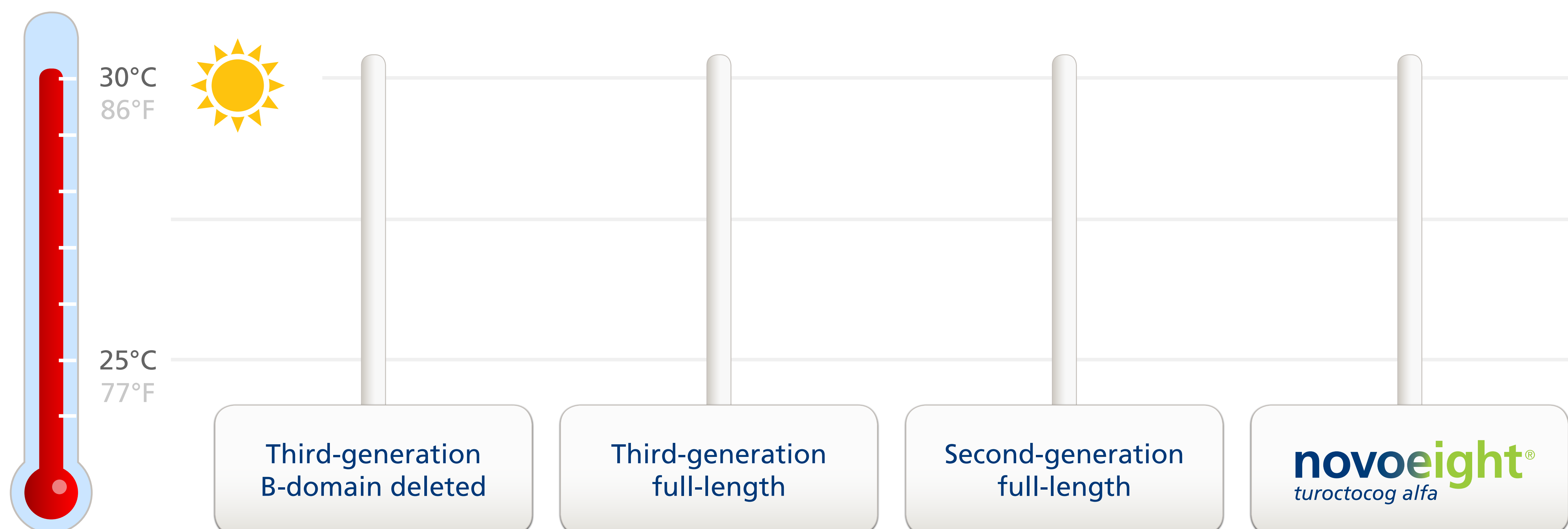


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# Only NovoEight® can be stored at 30°C for up to 1 year<sup>1,17-19</sup>

Room temperature stability for an active lifestyle<sup>1</sup>

## Maximum storage temperature and duration by product<sup>1,17-19</sup>



Store in original package in order to protect from light.<sup>1</sup>



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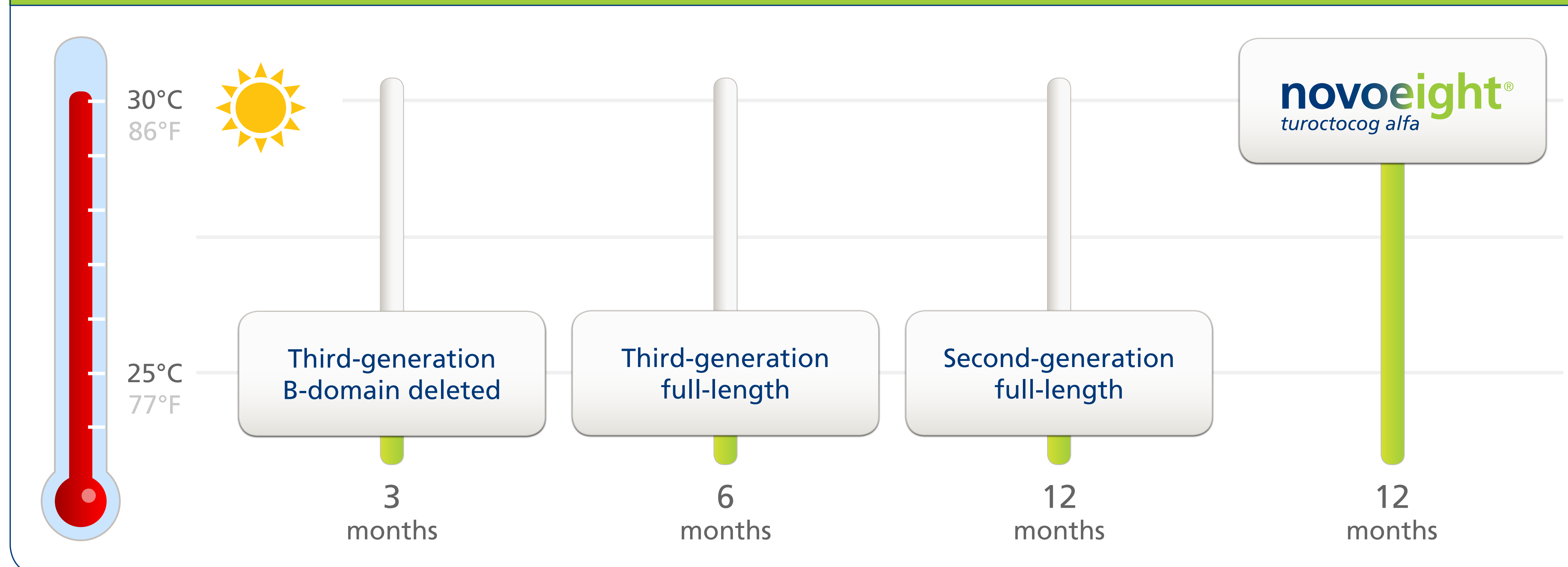
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Room temperature stability for an active lifestyle<sup>1</sup>

Only NovoEight® can be stored at

**30°C**  
for up to  
**1 year**

Maximum storage temperature and duration by product<sup>1,17-19</sup>



**80% of patients and caregivers prefer** a FVIII that offers storage at a higher temperature for longer durations<sup>30</sup>

Store in original package in order to protect from light.<sup>1</sup>



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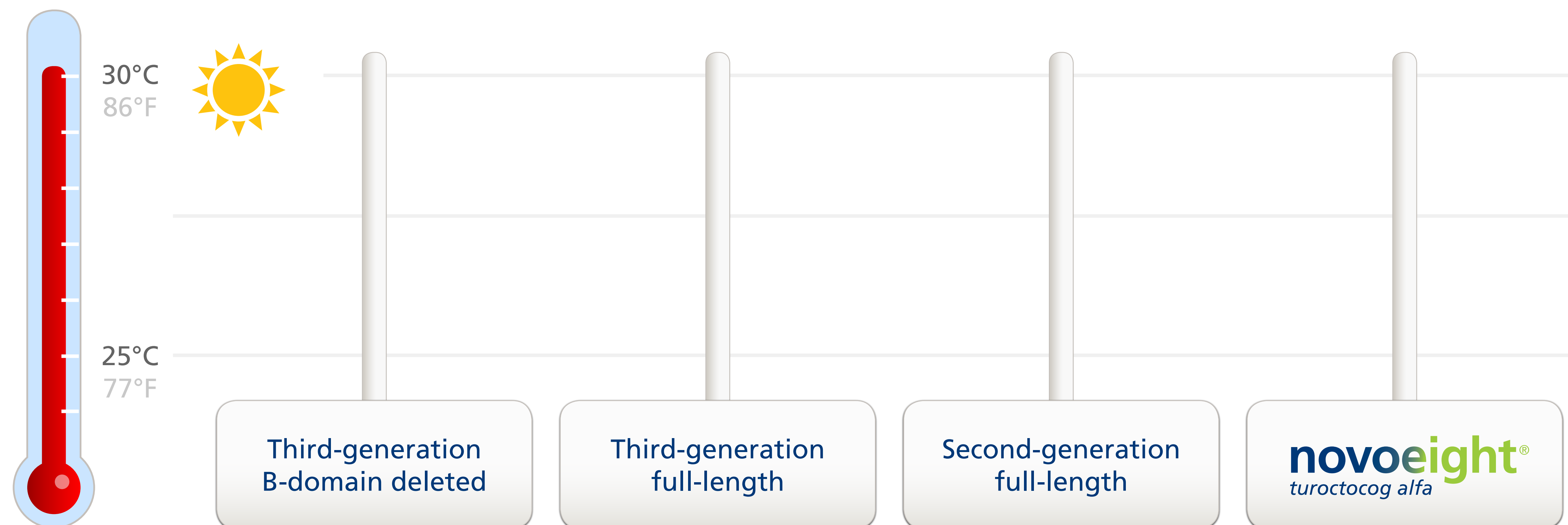


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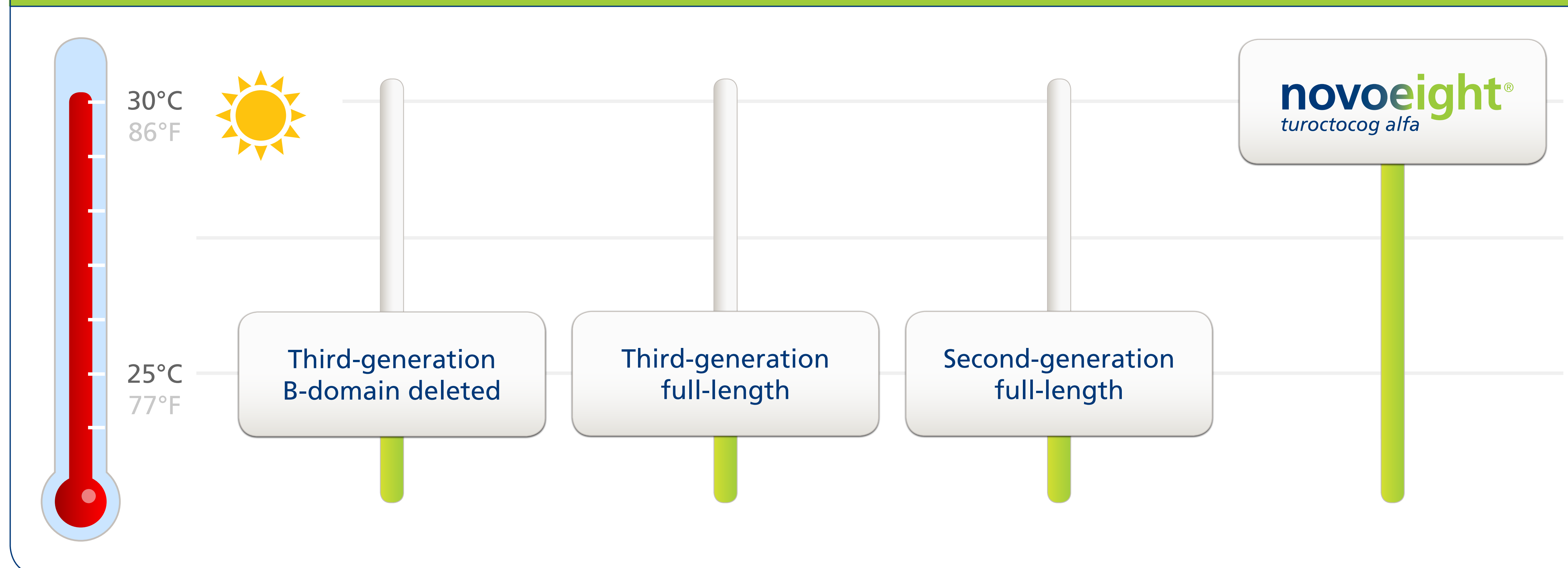
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Room temperature stability for an active lifestyle

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## Maximum storage temperature by product



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# NovoEight® offers easy reconstitution and multiple dose strengths

**Easy reconstitution** facilitates quick preparation of treatment<sup>1\*</sup>

- Pre-filled syringe with 4 ml solvent

**Multiple dose strengths** help more patients infuse with fewer vials<sup>1</sup>



Note: Image is for placement only. Please update with approved image upon receipt.

\*Compared with vial-to-vial reconstitution.



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# Novo Nordisk: **innovation and services** that support you and your patients

Engineering therapeutic proteins since 1923<sup>20</sup>

Long-standing global commitment to the haemophilia community<sup>31</sup>

Committed to providing support and services



**Lawrence, 19 years old**, is planning to attend university to study physics. He is a full-time lifeguard and enjoys spending time with his mother. Lawrence lives with haemophilia A.



R

SPC

**novoeight**<sup>®</sup>  
turoctocog alfa



Regions/countries to update with local services



Introduction
Reliability
Purity and Safety
Portability
Innovation and Services
Summary

# NovoEight® is designed to fit into his world

*Julian, 25 years old, is studying for a career in social work and enjoys working with children as a camp counsellor. Julian lives with haemophilia A.*

NovoEight®, the **first new rFVIII** molecule in over a decade,<sup>1,4–9</sup> is deliberately designed for:

## RELIABILITY

- Consistent activity from batch to batch<sup>1,10</sup>
- Efficacy proven in the largest pivotal trial programme of any approved rFVIII (N=213)<sup>1,11</sup>

## PURITY AND SAFETY

- Five-step purification process including unique immunoaffinity chromatography and nanofiltration<sup>4,12</sup>
- Well tolerated in clinical trials<sup>1,15,16</sup>

## PORTABILITY

- Enhanced room temperature stability<sup>1</sup>



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NovoEight®, the **first new rFVIII** molecule in over a decade,<sup>1,4–9</sup> is deliberately designed for:

## RELIABILITY

PTPs who switched to NovoEight® in pivotal trials developed

**0** INHIBITORS<sup>1\*</sup>

## PURITY AND SAFETY

First rFVIII to use a

**20** NM FILTER<sup>12–14</sup>

## PORTABILITY

The only rFVIII with storage at

**30°** CELSIUS<sup>1,17–19</sup>

PTP=previously treated patient.

\*Patients with previous inhibitors were excluded from the trials. Individuals with haemophilia A may develop inhibitors to FVIII. Monitor patients taking NovoEight® for inhibitor formation.<sup>1,20</sup>

NovoEight® is a registered trademark owned by Novo Nordisk Health Care AG.  
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