WHAT IS ESPEROCT®?

Esperoct® [antihemophilic factor (recombinant), glycopegylated-exei] is an injectable medicine to treat and prevent or reduce the number of bleeding episodes in people with hemophilia A. Your healthcare provider may give you Esperoct® when you have surgery.

- Esperoct® is not used to treat von Willebrand Disease

Move beyond the threshold

Esperoct® can give you high factor levels for longer.

*Of 1% trough factor levels for standard half-life (SHL) products in adults and adolescents.

*Compared with SHL products.

Please see Important Safety Information throughout.
Please see accompanying Prescribing Information.
Extend half-life beyond the standard

22-hour average half-life in adults

60% longer half-life compared to SHL products

Factor levels stay at or above 3% for 100% of the time<sup>c,d</sup>

Factor levels stay at or above 5% for 90% of the time<sup>c,d</sup>

Esperoct<sup>®</sup> is made by taking the existing Novoeight<sup>®</sup> (rFVIII) molecule and adding PEGylation technology to extend the half-life

Level up prophylaxis with a simple dose

High factor levels from one dose to the next

Switching made easy with a standard 50 IU/kg dose every 4 days

No dose adjustment needed

For adults and adolescents

IMPORTANT SAFETY INFORMATION

Who should not use Esperoct<sup>®</sup>?

- You should not use Esperoct<sup>®</sup> if you are allergic to factor VIII or any of the other ingredients of Esperoct<sup>®</sup> or if you are allergic to hamster proteins

Please see additional Important Safety Information throughout. Please see accompanying Prescribing Information.

0 1 2 3 4 5 6 7

FVIII activity (%)

0 50 100 150

Time (days)

Esperoct<sup>®</sup> 50 IU/kg

Standard rFVIII

rFVIII=recombinant factor VIII.

<sup>a</sup>Data shown are from 42 adults who received a pharmacokinetic (PK) assessment around the first Esperoct<sup>®</sup> 50 IU/kg dose.

<sup>b</sup>Data shown are from a comparison study of 36 previously treated patients (FVIII) 18 years or older who received a 25, 50, or 75 IU/kg dose of their previous SHL product followed by the same dose of Esperoct<sup>®</sup>. To allow for comparison, all results were adjusted to a 50 IU/kg dose of each product.

<sup>c</sup>Trough level goal is 1% for prophylaxis.

<sup>d</sup>Data shown are from a study where 175 previously treated adolescents and adults received routine prophylaxis with Esperoct<sup>®</sup> 50 IU/kg every 4 days for 76 weeks. Pre-dose factor activity (trough) levels were evaluated at follow-up visits. Mean trough levels for adolescents (12-<18 years) were 2.7 IU/dL.

<sup>e</sup>Steady-state factor VIII (FVIII) activity levels were estimated in 143 adults and adolescents using PK modeling.

<sup>f</sup>Extended half-life compared to SHL products.

<sup>g</sup>Data shown are from a comparison study of 26 previously treated patients (PTPs) 18 years or older who received a 25, 50, or 75 IU/kg dose of their previous SHL product followed by the same dose of Esperoct<sup>®</sup>. To allow for comparison, all results were adjusted to a 50 IU/kg dose of each product.
Stay protected from bleeds

Dose less often\(^a\) without sacrificing protection

<table>
<thead>
<tr>
<th>Overall bleeds per year(^b)</th>
<th>Joint bleeds per year(^b)</th>
<th>Spontaneous bleeds per year(^b)</th>
<th>Traumatic bleeds per year(^b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2</td>
<td>0.9</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

\(^a\) Compared to SHL products, 50% fewer infusions when administered every other day and 40% fewer when administered 3x weekly.

\(^b\) 175 PTPs with severe hemophilia A received Esperoct\(^\text{®}\) 50 IU/kg every 4 days for 76 weeks based on median annualized bleed rates shown.

IMPORTANT SAFETY INFORMATION

What is the most important information I need to know about Esperoct\(^\text{®}\)?

- Do not attempt to do an infusion yourself unless you have been taught how by your healthcare provider or hemophilia treatment center.
- Call your healthcare provider right away or get emergency treatment right away if you get any signs of an allergic reaction, such as: hives, chest tightness, wheezing, dizziness, difficulty breathing, and/or swelling of the face.

Prepare for the unexpected

Control for the treatment of bleeding episodes

Dosing for the treatment of bleeding episodes

- 40 IU/kg for minor to moderate bleeds
- 50 IU/kg for major bleeds

For moderate to major bleeds, additional dose(s) may be administered every 24 hours.

97% of bleeds controlled with 1-2 infusions\(^c,d\)

- Data shown are from a study where 12 adult and adolescent PTPs with severe hemophilia chose to be treated on demand and received Esperoct\(^\text{®}\) for 532 bleeding episodes.

Dose less often\(^a\) without sacrificing protection

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For adults and adolescents

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Switching made easy

One standard dose makes it easy to switch at any age

**65 IU/kg twice weekly**

Fewer infusions per year compared with SHL dosing regimens

No dose adjustment needed.

Because FVIII products may be cleared from the body faster in children <12 years, higher and more frequent dosing may be needed.

*Internal can be adjusted based on individual response to treatment.

**IMPORTANT SAFETY INFORMATION**

What should I tell my healthcare provider before using Esperoct®?

• Before taking Esperoct®, you should tell your healthcare provider if you have or have had any medical conditions, take any medicines (including non-prescription medicines and dietary supplements), are nursing, pregnant or planning to become pregnant, or have been told that you have inhibitors to factor VIII.

Please see additional Important Safety Information throughout.

Please see accompanying Prescribing Information.

Protection that keeps up with them

**Esperoct® achieved a 14.3-hour average half-life in children**

**85% longer half-life compared to SHL**

Low number of bleeds per year for children aged 0-<12 years

2.0 Overall bleeds per year

0 Joint bleeds

**Fewer infusions per year compared with SHL dosing regimens**

**FEWER INFUSIONS**

- 43% fewer infusions if your child previously infused every other day
- 33% fewer infusions if your child previously infused 3x/week

65 IU/kg twice weekly

Less annualized bleeding rates:

- **0.20 Joint bleeds per year**
- **0.10 Spontaneous bleeds per year**
- **0.10 Traumatic bleeds per year**

*Comparison to prior FVIII product was performed at the beginning of the study in previously treated children. The geometric mean terminal half-life in 23 children aged 0-<12 years was 14.3 hours. Esperoct® geometric mean terminal half-life was 14.7 hours in 12 children aged 0-6 and 13.8 hours in 10 children aged 6-11.

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Comparison to prior FVIII product was performed at the beginning of the study in previously treated children. Esperoct® half-life was 14.3 hours in 12 children aged 0-<12 years. Esperoct® geometric mean terminal half-life was 14.7 hours in 12 children aged 0-5 and 13.8 hours in 10 children aged 6-11.

Data shown are from a study of 68 previously treated children (34 aged 0-5 and 34 aged 6-11) who received an average dose of approximately 65 IU/kg twice weekly for 26 weeks. Median annualized bleeding rates are shown.

For children (aged 0-<12 years)

**Esperoct® antihemophilic factor (recombinant), glycopegylated-exe**

**Org 39409 10**

**Please see additional Important Safety Information throughout.**

**Please see accompanying Prescribing Information.**
IMPORTANT SAFETY INFORMATION

What should I tell my healthcare provider before using Esperoct®? (cont’d)

• Your body can make antibodies called “inhibitors” against Esperoct®, which may stop Esperoct® from working properly. Call your healthcare provider right away if your bleeding does not stop after taking Esperoct®.

Count on a proven safety profile

Safety proven across 5 studies, the largest and longest EHL clinical trial program

- 0 blood clots
- No PEG-related safety concerns
- One PTP with a high-risk gene mutation developed an inhibitor to FVIII
  – Similar to the reported rate in patients with severe hemophilia A

EHL = extended half-life; PEG = polyethylene glycol.

An 18-year-old African-American male developed an inhibitor after 93 infusion days of Esperoct®. The inhibitor rose to 13.5 Bethesda units and the patient stopped participation in the study. There was no change in efficacy, and the inhibitor eventually went away on its own (without use of immune tolerance induction therapy).

- 80,000 infusion days
- 270 previously treated patients (PTPs)
- 0 blood clots
- No PEG-related safety concerns
- One PTP with a high-risk gene mutation developed an inhibitor to FVIII
  – Similar to the reported rate in patients with severe hemophilia A

IMPORTANT SAFETY INFORMATION

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• Your body can make antibodies called “inhibitors” against Esperoct®, which may stop Esperoct® from working properly. Call your healthcare provider right away if your bleeding does not stop after taking Esperoct®.

Designed to fit into your life

Compact packaging for easy storage

Small kit holds up to a week’s worth of factor

Based on a 70 kg person.

Please see additional Important Safety Information throughout. Please see accompanying Prescribing Information.
IMPORTANT SAFETY INFORMATION
What are the possible side effects of Esperoct®?
• Common side effects of Esperoct® include rash or itching, and swelling, pain, rash or redness at the location of infusion

Please see additional Important Safety Information throughout.
Please see accompanying Prescribing Information.
For adults, adolescents, and children

Considerations when switching to Esperoct®

You may be eligible for:

**Trial Program**

Talk to a NovoSecure™ specialist to find out if you’re eligible.

**Product Assistance Program**

Apply for the Product Assistance Program by calling 1-844-NOVOSEC (1-844-668-6732) for more information.

**Co-pay Assistance Program**

Get help with co-pay costs for Esperoct®

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*Patients who have been prescribed a Novo Nordisk hemophilia and rare bleeding disorder product for an FDA-approved indication, and who have commercial insurance, may be eligible to receive a limited supply of free product. Patients who participate in any government, state, or federally funded medical or prescription benefit programs, including Medicare, Medicaid, Medigap, VA, DOD, and TRICARE, including patients who participate in a managed Medicaid program or have Medicaid as secondary insurance, are not eligible to receive product support. Product is provided at no cost to the patient or the HCP if the HCP pays not less than the lowest price offered for an equal product by the HCP to other patients. (1) all third party for the free product, or (2) resell the free product.

The Novo Nordisk Patient Assistance Program (PAP) is administered by NovoSecure™. To qualify for the PAP, patients must demonstrate financial need and must have attempted to find alternative reimbursement. Several factors are considered in evaluating financial need, including cost of living, size of household, and burden of total medical expenses. If the applicant qualifies under the PAP guidelines, a limited supply of the requested medications will be shipped to the patient. Patients who qualify for PAP may be eligible to receive the prescribed Novo Nordisk product, for up to 1 year from the approval date. Product limits vary.

Novo Nordisk Hemophilia and Rare Bleeding Disorders Copay/Coinsurance Terms and Conditions: Enrolled patients are eligible for up to $12,000 in copay/coinsurance assistance per calendar year for each Novo Nordisk hemophilia or rare bleeding disorder product. Assistance is retroactive to 60 days. Patients must be commercially insured and may not be participating in any government, state, or federally funded medical or prescription benefit programs, including Medicare, Medicaid, Medigap, VA, DOD, and TRICARE, including patients who participate in a managed Medicaid program or have Medicaid as secondary insurance. Uninsured, cash-paying patients are not eligible to participate. Patients are eligible to receive copay/coinsurance assistance on an annual basis (12 months). Offer good only in the USA, Puerto Rico, Guam, Saipan, and Virgin Islands with participating pharmacies and cannot be redeemed at government-subsidized clinics. Void where taxed, restricted or prohibited by law. Absent of a change in Massachusetts law, effective July 1, 2019, the Savings Card will no longer be valid for residents of Massachusetts. Patient is responsible for complying with any insurance carrier co-payment/coinsurance requirements, including disclosing any savings received from this program. Re-confirmation of information may be requested periodically to ensure accuracy of data and compliance with terms. This is not an insurance program. Novo Nordisk reserves the right to revoke, reverse, or amend this offer without notice at any time. Non-medication expenses, such as ancillary supplies or administration-related costs, are not eligible. Must have a current prescription for an FDA-approved indication.

IMPORTANT SAFETY INFORMATION

Who should not use Esperoct®?

- You should not use Esperoct® if you are allergic to factor VIII or any of the other ingredients of Esperoct® or if you are allergic to hamster proteins.
**Move beyond the threshold**

Fewer infusions per year compared with SHL for adults and adolescents

- 50% fewer infusions if previously infused every other day
- 40% fewer infusions if previously infused 3x/week

**High factor levels in adults and adolescents**

- At or above 3% for 100% of the time
- At or above 5% for 90% of the time

**Flexible on the go**

- The only EHL product with stability up to 104°F

**The largest and longest EHL clinical trial program**

- Of 1% trough factor levels for SHL products in adults and adolescents.
- Data shown are from 42 adults who received a PK assessment around the first Esperoct® 50 IU/kg dose.
- Data shown are from a study where 175 previously treated adolescents and adults received routine prophylaxis with Esperoct® 50 IU/kg every 4 days for 76 weeks. Pre-dose factor activity (trough) levels were evaluated at follow-up visits. Mean trough levels for adolescents (12-<18 years) were 2.7 IU/dL.
- Steady-state FVIII activity levels were estimated in 143 adults and adolescents using PK modeling.
- For up to 3 months.

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