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

novo nordisk®

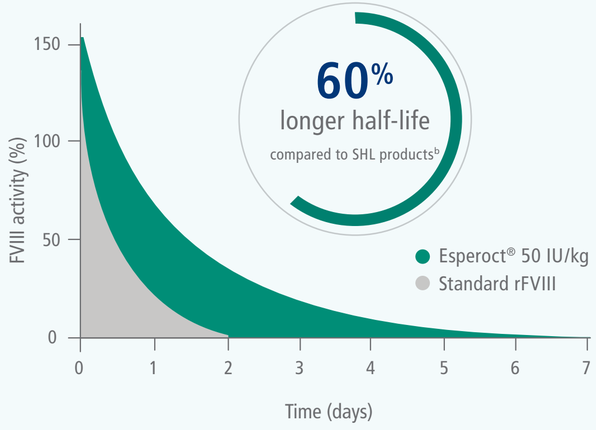
Please see Important Safety Information throughout.
Please click here for Prescribing Information.

esperoct®
antihemophilic factor (recombinant), glycopegylated-exei

Click here will link to https://www.novo-pi.com/esperoct.pdf

Extend half-life **beyond the standard**

22-hour average half-life in adults[a]



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

Half-life=the time it takes for the level of factor in your blood to fall by 50% (half) after an infusion.
rFVIII=recombinant factor VIII.
SHL=standard half-life.

[a]Data shown are from 42 adults who received a pharmacokinetic (PK) assessment around the first Esperoct® 50 IU/kg dose.
[b]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®. To allow for comparison, all results were adjusted to a 50 IU/kg dose of each product.

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

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Level up prophylaxis with **a simple dose**

High factor levels from one dose to the next

Factor levels stay **at or above 3%** for **100%** of the time[c,d]

Factor activity between 1% - 5% is defined as moderate hemophilia

Factor levels stay **at or above 5%** for **90%** of the time[c,e]

Factor activity 5% and above is defined as mild hemophilia

Switch to fewer infusions than SHLs

with a standard **50 IU/kg dose every 4 days**

No dose adjustment needed

50% **FEWER INFUSIONS** if you previously infused **every other day**

Fewer infusions per year compared with SHL dosing regimens

40% **FEWER INFUSIONS** if you previously infused **3x/week**

[c]Trough level goal is 1% for prophylaxis.
[d]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.
[e]Steady-state factor VIII (FVIII) activity levels were estimated in 143 adults and adolescents using PK modeling.

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Stay protected from bleeds

Dose less often[a] without sacrificing protection

1.2 Overall bleeds per year[b]

0.9 Joint bleeds per year[b]

0 Spontaneous bleeds per year[b]
Traumatic bleeds per year[b]

Long-term trial results – up to 6.6 years[c]

0.8 Overall bleeds per year[c]
N=177

[a]Compared to SHL products, 50% fewer infusions when administered every other day and 40% fewer when administered 3x weekly.
[b]Data shown are from the main phase of a study of 175 previously treated people aged ≥12 years with severe hemophilia A who received Esperoct® 50 IU/kg every 4 days for 76 weeks. Median annualized bleeding rates are shown.
[c]Median annualized bleeding rate shown is from the main and extension phases of the pivotal clinical trial of previously treated people aged ≥12 years with severe hemophilia A who received Esperoct® 50 IU/kg every 4 days, for up to 6.6 years.

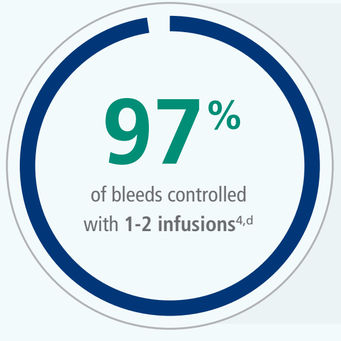
IMPORTANT SAFETY INFORMATION

What is the most important information I need to know about Esperoct®?

- **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

[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® for 532 bleeding episodes.

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Protection that keeps up with children

Esperoct® achieved a

14.3-hour
average half-life in children[a]

85% longer
half-life compared to SHL[b]

Factor levels stay
at or above 2% for
Factor activity between 1% - 5%
is defined as moderate hemophilia

Aged 6 to 11 years
100%
of the time[c,d]

SHL=standard half-life.

[a]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 ages 0-5 and 13.8 hours in 10 children ages 6-11.
[b]Comparison to prior FVIII product was performed at the beginning of the study in previously treated children. Esperoct® half-life was 14.7 hours in 12 children ages 0-6 and 13.8 hours in 10 children ages 6-11.
[c]Trough level goal is 1% for prophylaxis.
[d]Data shown are from a study where 34 previously treated children received routine prophylaxis with Esperoct® 60 IU/kg (50-75 IU/kg) twice weekly. Pre-dose factor activity (trough) levels were evaluated at follow-up visits.

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

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Reduce bleeding episodes

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

2.0 Overall bleeds per year[e]

0 Joint bleeds
Spontaneous bleeds
Traumatic bleeds[e]

Long-term trial results – up to 5.4 years[f]

0.8 Overall bleeds per year[f]
N=68

100% resolution of target joints[g]

[e]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.
[f]Median annualized bleeding rate shown is from the main and extension phases of the clinical trial in previously treated children with severe hemophilia A, for a median of 5 years.
[g]A target joint was defined as a single joint with ≥3 bleeding episodes in 6 consecutive months. All baseline target joints reached definition of target joint resolution (if there were no bleeding episodes for 12 consecutive months) in slightly over 2 years of treatment with Esperoct®. Twelve patients with 16 documented target joints at baseline participated in the main and extension phases of the clinical trial.

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Simple dosing with **fewer** infusions than SHLs

One standard dose makes it easy to switch

65 IU/kg twice weekly

No dose adjustment needed[a]

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

43% **FEWER INFUSIONS** if your child previously **infused every other day**

Fewer infusions per year compared with SHL dosing regimens

33% **FEWER INFUSIONS** if your child previously **infused 3x/week**

[a]Interval can be adjusted based on individual response to treatment.

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®**

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

270 previously treated patients (PTPs) over **80,000** infusion days

Safety proven across 5 clinical studies

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

EHL=extended half-life.
[b]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).

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Flexible on the go
- even when it gets above 86˚F and up to 104˚F

Can be stored up to **86˚F** up to **12 months**

Can be stored from **86˚F -104˚F** up to **3 months**

After reconstitution:
Can be used up to
4 hours at up to **86˚F**

The **EHL** product with the **highest** storage temperature for the **longest** time

Designed to fit into your life

Compact packaging for easy storage

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

Ready in **3 simple steps**

A prefilled syringe provides convenient administration in 2 minutes

Attach
Prefilled diluent syringe contains 4 mL of diluent—works with any dose strength

Twist
Adapter connects the syringe and vial with a 25 µm inline particle filter

Mix
After mixing, the reconstituted solution can be administered

5 vial sizes for personalized treatment

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Considerations when switching to Esperoct®

You may be eligible for:

Free Trial Product Program

Talk to a [NovoSecure™] specialist to find out if you're eligible[a]

Product Assistance Program

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

Co-pay Assistance Program

Get help with co-pay costs for Esperoct®, up to $12,000[c]

Visit [MyNovoSecure.com] or call [1-844-NOVOSEC] (1-844-668-6732) to speak with a [NovoSecure™] specialist

[a]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, is not contingent on any product purchase, and the patient and HCP must not: (1) bill any third party for the free product, or (2) resell the free product.

[b]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 medication(s) 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.

[c]Novo Nordisk Hemophilia and Rare Bleeding Disorders Copay/Coinsurance Terms and Conditions: Enrolled patients are eligible for up to $12,000 in co-pay/coinsurance assistance per calendar year for each NNI 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 co-pay/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 disclosure 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 rescind, revoke, 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.

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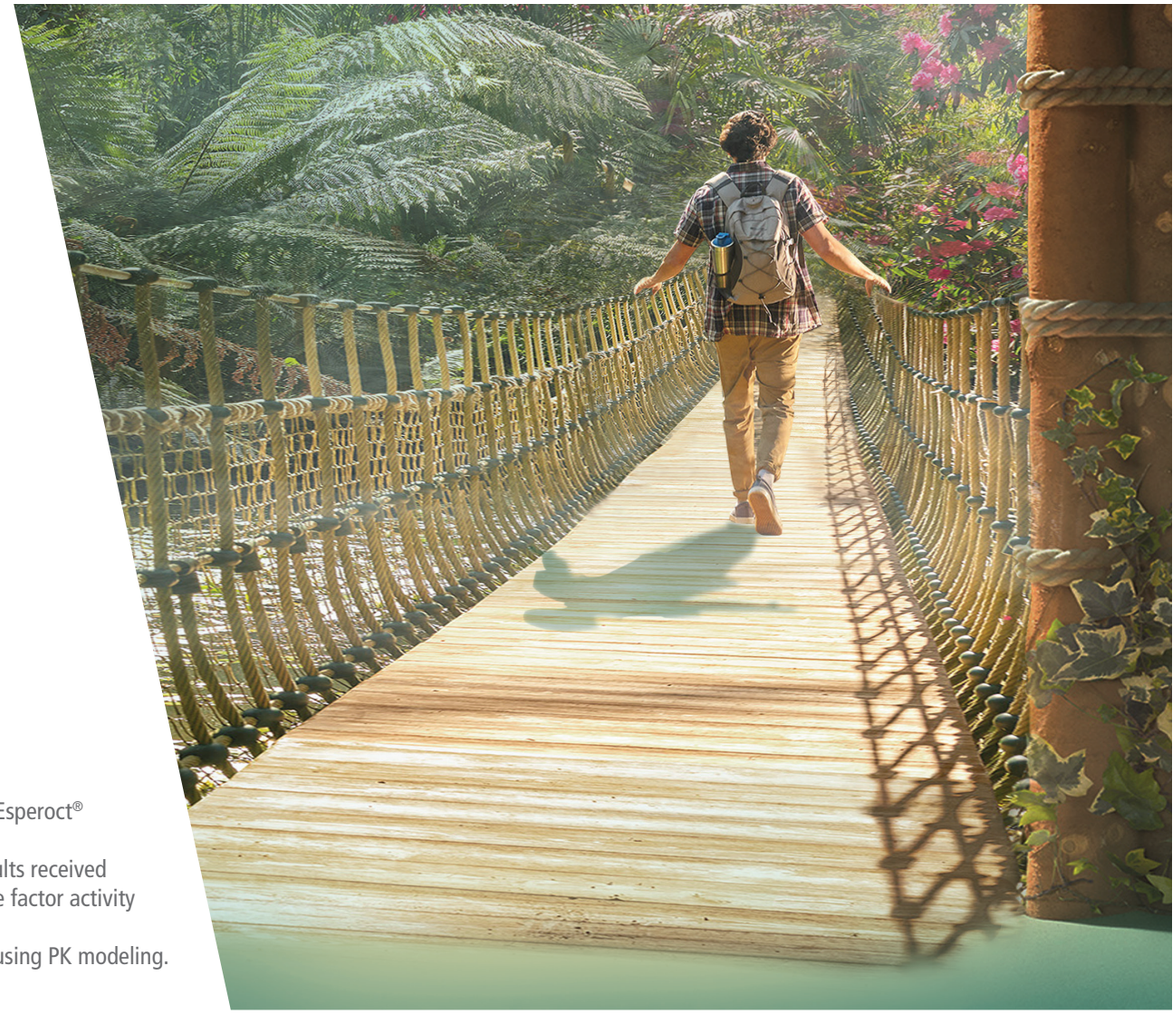
Move beyond the threshold[a]



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[b]

- Trough level at or above 3% for 100% of the time[c]
- Trough level at or above 5% for 90% of the time[d]

The only EHL product that can go with you from 86°F to 104°F[e]

The largest and longest EHL clinical trial program

[a]Of 1% trough factor levels for SHL products in adults and adolescents.
[b]Data shown are from 42 adults who received a PK assessment around the first Esperoct® 50 IU/kg dose.
[c]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.
[d]Steady-state FVIII activity levels were estimated in 143 adults and adolescents using PK modeling.
[e]For up to 3 months.

IMPORTANT SAFETY INFORMATION

What is the most important information I need to know about Esperoct®?

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Novo Nordisk Inc., 800 Scudders Mill Road, Plainsboro, New Jersey 08536 U.S.A.

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No matter what is happening today, your hemophilia A doesn't stop

Make sure your treatment can meet your needs

If you are considering switching to another treatment but are concerned with the contact related to in-person appointments

Consider these features of Esperoct®

- Fixed dosing of 50 IU/kg every 4 days with no dose adjustment required for adults and adolescents
- Follow-up pharmacokinetic testing may not be routinely needed
- Free trial product sent directly to you after your doctor prescribes Esperoct®[a]

From samples to support, Novo Nordisk is committed to making starting and continuing treatment with Esperoct® right for you, at the doctor's office and at home.

[a]Visit MyNovoSecure.com for more details about this program and eligibility requirements.

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Move beyond the threshold[a]

With **Esperoct®**, an extended half-life factor VIII replacement therapy that

Offers **proven protection** against bleeds
- Dose less often without sacrificing protection
  - 1.2 overall bleeds per year in adults and adolescents[b]
  - Long-term trial results show 0.8 overall bleeds per year[c]

Achieves **high factor levels** in adults and adolescents[d]
- Trough levels at or above 3% for 100% of the time[e]
- Trough levels at or above 5% for 90% of the time[f]

Is committed to **safety**
- Has the largest and longest EHL clinical trial program
  - Proven across 5 clinical studies involving 270 previously treated patients

Requires up to 50% **fewer infusions than SHLs** per year for adults and adolescents
- 50% fewer infusions if previously infused every other day
- 40% fewer infusions if previously infused 3x/week

The only EHL product that can go with you from 86˚F to 104˚F[g]

[a]Of 1% trough factor levels for standard half-life (SHL) products in adults and adolescents.
[b]175 PTPs with severe hemophilia A received Esperoct® 50 IU/kg every 4 days for 76 weeks based on median annualized bleed rates shown.
[c]Median annualized bleeding rate shown is from the main and extension phases of the pivotal clinical trial of previously treated people aged ≥12 years with severe hemophilia A who received Esperoct® 50 IU/kg every 4 days, for up to 6.6 years.
[d]Data shown are from 42 adults who received a PK assessment around the first Esperoct® 50 IU/kg dose.
[e]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.
[f]Steady-state FVIII activity levels were estimated in 143 adults and adolescents using PK modeling.
[g]For up to 3 months.

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