# Vital Link

## ...For Hoosiers Living with a Bleeding Disorder

HEMOPHILIA OF INDIANA

June 2021

The Vital Link is published quarterly by Hemophilia of Indiana, Inc.

Designed by: Kristy McConnell



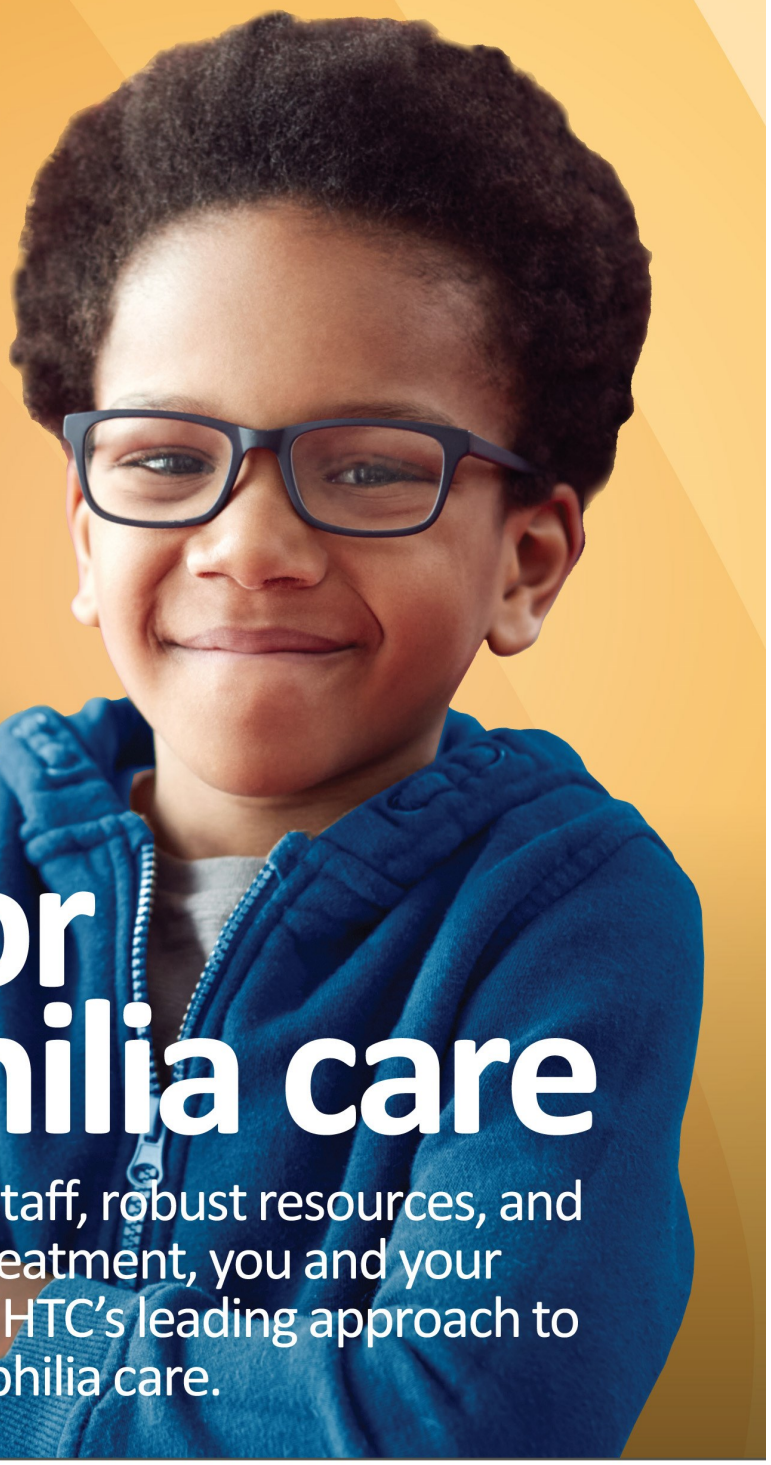
Hemophilia of Indiana
6910 N. Shadeland Ave.
Suite 140
Indianapolis, IN 46220
(317) 570-0039
(800) 241-2873
www.hoii.org

### 2021 Camp Brave Eagle!!

Camp is back!! The 2021 Camp Brave Eagle was held June 13 - 18 at the YMCA Camp Crosley. This year marks the return of in person camp after 2020 Camp Brave Eagle was held virtually due to the pandemic. Camp Brave Eagle, founded in 1999, allows children with a bleeding disorder experience the "traditional" summer camp experience. Camp Brave Eagle encourages self-sufficiency, builds confidence, increase campers' self-esteem, and promotes an overall positive outlook. Campers participate in a variety of camp activities that includes archery, swimming, canoeing, a high ropes course, and much more! In addition, campers are also given the chance to earn their "Big Stick" by learning self-infusion training. This year Camp Brave Eagle hosted 90 campers! Due to the pandemic regulations, siblings were not allowed to attend camp this year, but hoping to bring them back next year! Hemophilia of Indiana would like to thank all of our donors and sponsors that allows us to provide this incredible experience to our young members of the bleeding disorders community!

## More pictures from 2021 Camp Brave Eagle…


Indiana Hemophilia & Thrombosis Center



# Your medical home for hemophilia care

From our compassionate staff, robust resources, and commitment to tailored treatment, you and your family will find comfort in IHTC's leading approach to a lifetime of quality hemophilia care.

## Indiana's only Center of Excellence for bleeding and clotting disorders

The Indiana Hemophilia & Thrombosis Center (IHTC) is the state's only federally-designated Hemophilia Treatment Center and the first HTC in the U.S. to receive national medical home certification. We offer comprehensive bleeding disorder care, all at one center. All members of IHTC's clinical care team have extensive experience and deep expertise in bleeding disorders. This offers our patients the comfort and convenience of having every aspect of their bleeding disorder care all in one location. Visit ihtc.org

Indiana Hemophilia & Thrombosis Center, Inc. | 8326 Naab Road | Indianapolis, IN 46260 | 877.CLOTTER


**What is HEMLIBRA?**

HEMLIBRA is a prescription medicine used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children, ages newborn and older, with hemophilia A with or without factor VIII inhibitors.

**What is the most important information I should know about HEMLIBRA?**

**HEMLIBRA increases the potential for your blood to clot. People who use activated prothrombin complex concentrate (aPCC; Feiba®) to treat breakthrough bleeds while taking HEMLIBRA may be at risk of serious side effects related to blood clots.**

**These serious side effects include:**

- **Thrombotic microangiopathy (TMA),** a condition involving blood clots and injury to small blood vessels that may cause harm to your kidneys, brain, and other organs
- **Blood clots (thrombotic events),** which may form in blood vessels in your arm, leg, lung, or head

Please see Brief Summary of Medication Guide on following page for Important Safety Information, including **Serious Side Effects**.

HEMLIBRA®
emicizumab-kxwh
injection for subcutaneous use

# Medication Guide
# HEMLIBRA® (hem-lee-bruh) (emicizumab-kxwh) injection, for subcutaneous use

## What is the most important information I should know about HEMLIBRA?

**HEMLIBRA increases the potential for your blood to clot. Carefully follow your healthcare provider's instructions regarding when to use an on-demand bypassing agent or factor VIII (FVIII) and the recommended dose and schedule to use for breakthrough bleed treatment.**

**HEMLIBRA may cause the following serious side effects when used with activated prothrombin complex concentrate (aPCC; FEIBA®), including:**

- **Thrombotic microangiopathy (TMA).** This is a condition involving blood clots and injury to small blood vessels that may cause harm to your kidneys, brain, and other organs. Get medical help right away if you have any of the following signs or symptoms during or after treatment with HEMLIBRA:
  - confusion
  - weakness
  - swelling of arms and legs
  - yellowing of skin and eyes
  - stomach (abdomen) or back pain
  - nausea or vomiting
  - feeling sick
  - decreased urination
- **Blood clots (thrombotic events).** Blood clots may form in blood vessels in your arm, leg, lung, or head. Get medical help right away if you have any of these signs or symptoms of blood clots during or after treatment with HEMLIBRA:
  - swelling in arms or legs
  - pain or redness in your arms or legs
  - shortness of breath
  - chest pain or tightness
  - fast heart rate
  - cough up blood
  - feel faint
  - headache
  - numbness in your face
  - eye pain or swelling
  - trouble seeing

**If aPCC (FEIBA®) is needed, talk to your healthcare provider in case you feel you need more than 100 U/kg of aPCC (FEIBA®) total.**

See "**What are the possible side effects of HEMLIBRA?**" for more information about side effects.

## What is HEMLIBRA?

HEMLIBRA is a prescription medicine used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children, ages newborn and older, with hemophilia A with or without factor VIII inhibitors.

Hemophilia A is a bleeding condition people can be born with where a missing or faulty blood clotting factor (factor VIII) prevents blood from clotting normally.

HEMLIBRA is a therapeutic antibody that bridges clotting factors to help your blood clot.

## Before using HEMLIBRA, tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant. It is not known if HEMLIBRA may harm your unborn baby. Females who are able to become pregnant should use birth control (contraception) during treatment with HEMLIBRA.
- are breastfeeding or plan to breastfeed. It is not known if HEMLIBRA passes into your breast milk.

**Tell your healthcare provider about all the medicines you take,** including prescription medicines, over-the-counter medicines, vitamins, or herbal supplements. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

## How should I use HEMLIBRA?

**See the detailed "Instructions for Use" that comes with your HEMLIBRA for information on how to prepare and inject a dose of HEMLIBRA, and how to properly throw away (dispose of) used needles and syringes.**

- Use HEMLIBRA exactly as prescribed by your healthcare provider.
- **Stop (discontinue) prophylactic use of bypassing agents the day before starting HEMLIBRA prophylaxis.**
- **You may continue prophylactic use of FVIII for the first week of HEMLIBRA prophylaxis.**
- HEMLIBRA is given as an injection under your skin (subcutaneous injection) by you or a caregiver.
- Your healthcare provider should show you or your caregiver how to prepare, measure, and inject your dose of HEMLIBRA before you inject yourself for the first time.
- Do not attempt to inject yourself or another person unless you have been taught how to do so by a healthcare provider.
- Your healthcare provider will prescribe your dose based on your weight. If your weight changes, tell your healthcare provider.
- You will receive HEMLIBRA 1 time a week for the first four weeks. Then you will receive a maintenance dose as prescribed by your healthcare provider.
- If you miss a dose of HEMLIBRA on your scheduled day, you should give the dose as soon as you remember. You must give the missed dose as soon as possible before the next scheduled dose, and then continue with your normal dosing schedule. **Do not** give two doses on the same day to make up for a missed dose.
- HEMLIBRA may interfere with laboratory tests that measure how well your blood is clotting and may cause a false reading. Talk to your healthcare provider about how this may affect your care.

## What are the possible side effects of HEMLIBRA?

- See "**What is the most important information I should know about HEMLIBRA?**"

**The most common side effects of HEMLIBRA include:**

- redness, tenderness, warmth, or itching at the site of injection
- headache
- joint pain

These are not all of the possible side effects of HEMLIBRA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

## How should I store HEMLIBRA?

- Store HEMLIBRA in the refrigerator at 36°F to 46°F (2°C to 8°C). Do not freeze.
- Store HEMLIBRA in the original carton to protect the vials from light.
- Do not shake HEMLIBRA.
- If needed, unopened vials of HEMLIBRA can be stored out of the refrigerator and then returned to the refrigerator. HEMLIBRA should not be stored out of the refrigerator for more than a total of 7 days or at a temperature greater than 86°F (30°C).
- After HEMLIBRA is transferred from the vial to the syringe, HEMLIBRA should be used right away.
- Throw away (dispose of) any unused HEMLIBRA left in the vial.

**Keep HEMLIBRA and all medicines out of the reach of children.**

## General information about the safe and effective use of HEMLIBRA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use HEMLIBRA for a condition for which it was not prescribed. Do not give HEMLIBRA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about HEMLIBRA that is written for health professionals.

## What are the ingredients in HEMLIBRA?

**Active ingredient:** emicizumab-kxwh

**Inactive ingredients:** L-arginine, L-histidine, poloxamer 188, and L-aspartic acid.

Manufactured by: Genentech, Inc., A Member of the Roche Group,
1 DNA Way, South San Francisco, CA 94080-4990
U.S. License No. 1048

For more information, go to www.HEMLIBRA.com or call 1-866-HEMLIBRA.
This Medication Guide has been approved by the U.S. Food and Drug Administration
Revised: 10/2018




Genentech
*A Member of the Roche Group*

# 2021 Bowling For Bleeding Disorders

After having to be cancelled in 2020, Bowling for Bleeding Disorders returned in person on Saturday, April 17th! Bowling for Bleeding Disorders is a community event and fundraiser for the Judy Moore Memorial Scholarship Program. A special thank you to Jennifer Maas from the Indiana Hemophilia & Thrombosis Center for providing an interactive and entertaining education program! 14 teams competed against each other in bowling style trivia contest testing their knowledge on bleeding disorders as well as Hemophilia of Indiana and the Indiana Hemophilia & Thrombosis Center! HoII would like to thank all of our sponsors and teams that came out to support the Judy Moore Scholarship Program and the bleeding disorders community of Indiana!

# How Caregivers Can Care for Themselves

**Caregivers devote themselves to the well-being of others, but to be their best they need to practice self-care**

Author: Michael Hickey

Fitness & Nutrition

Being a caregiver for an adult with a chronic condition is hard, and can be emotionally exhausting. It can result in a range of feelings, from loneliness, sadness and fear to anger, worry and guilt. Plus, such high levels of stress can lead to anxiety and depression, weaken the immune system, and increase your risk of serious chronic illnesses such as heart disease and arthritis.

This is why caregivers need to remind themselves that they need care, too, and should give themselves the opportunity to rest and rejuvenate. Here are four self-care tips that can prevent caregiver burnout and fatigue, even during the age of social distancing.

**Reach Out for Help**

Caregivers put a lot of responsibility on their shoulders, but that doesn't mean they need to carry the emotional burden themselves. Be willing to accept assistance and reach out to a psychologist or mental health professional to help deal with your stress and anxiety. With the pandemic, you may be hesitant to set up an in-person appointment, but there are still opportunities for virtual visits, and a wealth of mental health resources available online for free. Studies have shown that talking through your feelings with another person can have a significant positive impact on your mental health.

If you feel more comfortable talking to someone you know, don't be afraid to speak with a family member or close friend whom you trust to talk about your struggles.

**Take Advantage of Respite Care**

It might be hard to leave loved ones in the care of others even for a brief period, but respite care can give you a much-needed break. Respite care is when primary caregivers share the responsibility of caregiving—and get support for themselves—by leaving loved ones in the hands of professionals for a short period of time. Caregivers can do this by enlisting paid carers to watch a loved one in their home or by leaving a loved one in an out-of-home care facility, such as a nursing home or adult day care center. While their loved ones receive care from professionals, primary caregivers can rest, relax, see other family, take care of other responsibilities, or simply take a day to do something they enjoy.  The National Respite Network can help you find providers, programs and resources in your community.

Some services even offer in-home care, which could put you and your loved one at ease knowing they're in a familiar place.

**Manage Your Basic Needs**

When you're completely devoted to caring for another person, it can be easy to neglect your own health. But without a healthy diet, proper sleep and enough exercise, you won't be at your best, which means you may not have the capacity to effectively care for others. So don't ignore your body when your stomach growls; grab a quick snack instead. Feel weak or shaky? Give yourself a few minutes to sit down and regroup. When you listen to your body, you and the person you care for will benefit.

**Practice Relaxation Techniques**

Practicing relaxation techniques such as deep breathing exercises, guided meditation, guided imagery, yoga and progressive muscle relaxation takes only minutes out of your day but can greatly reduce stress and improve your mood. And with smartphone apps such as Calm and free yoga classes online, you don't even have to leave your bedroom to get started.

Article courtesy of HEMAWARE: The Bleeding Disorders Magazine

# A **ONCE-WEEKLY** TREATMENT OPTION FOR HEMOPHILIA B.


To find out about a prescription option, talk to your doctor or visit

**OnceWeeklyForHemophiliaB.com**



Pfizer

# 2021 Course to Cure

The 2021 Course to a Cure Golf Outing was held on Monday, June 7th! This is the 37th year for the Course to a Cure Golf Outing held at the beautiful Maple Creek Golf & Country Club in Indianapolis, IN. After having to push back the event last year, we were excited to return the event to it's normal time in the first week of June! This year, we had 30 teams that participated and donated to Hemophilia of Indiana. After a rainy morning, the weather cooperated and allowed for a fun day of golf and fundraising for the bleeding disorders community of Indiana! Hemophilia of Indiana would like to thank all who donated and especially our sponsors that are vital to the success of the event!












When it comes to your hemophilia A treatment

# Move beyond the threshold[a]

Esperoct® can give you high factor levels for longer.[b]

## Extend half-life beyond the standard 22-hour average half-life in adults[c]

FOR ADULTS AND ADOLESCENTS

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

-50% fewer infusions if you previously infused every other day

-40% fewer infusions if you previously infused 3x a week

### High factor levels

At or above 3% for 100% of the time[d,e]

At or above 5% for 90% of the time[d,f]

### Flexible on the go

The ONLY extended half-life product that can be stored up to 104°F[g]

Please see Brief Summary for complete storage instructions.

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

[a]Of 1% trough factor levels for standard half-life (SHL) products in adults and adolescents.
[b]Compared with SHL products.
[c]Data shown are from 42 adults who received a pharmacokinetic (PK) assessment around the first Esperoct® 50 IU/kg dose.
[d]Trough level goal is 1% for prophylaxis.
[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. 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 pharmacokinetic modeling.
[g]For up to 3 months.

### 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

### 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

### 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

### 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
- 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®**

### 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 Brief Summary of Prescribing Information on the following page.**

Discover more at **Esperoct.com.**

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



**esperoct®**

*antihemophilic factor (recombinant), glycopegylated-exei*

# esperoct®

*antihemophilic factor (recombinant), glycopegylated-exei*

**Brief Summary information about ESPEROCT® [antihemophilic Factor (recombinant), glycopegylated-exei]**

This information is not comprehensive.

- Talk to your healthcare provider or pharmacist
- Visit www.novo-pi.com/esperoct.pdf to obtain FDA-approved product labeling
- Call 1-800-727-6500

**Patient Information**

**ESPEROCT®**
**[antihemophilic factor (recombinant), glycopegylated-exei]**

**Read the Patient Information and the Instructions For Use that come with ESPEROCT® before you start taking this medicine and each time you get a refill. There may be new information.**

This Patient Information does not take the place of talking with your healthcare provider about your medical condition or treatment. If you have questions about ESPEROCT® after reading this information, ask your healthcare provider.

## 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.**

You must carefully follow your healthcare provider's instructions regarding the dose and schedule for infusing ESPEROCT® so that your treatment will work best for you.

## What is ESPEROCT®?

ESPEROCT® is an injectable medicine used to replace clotting Factor VIII that is missing in patients with hemophilia A. Hemophilia A is an inherited bleeding disorder in all age groups that prevents blood from clotting normally.

ESPEROCT® is used 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.

## 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®
- if you are allergic to hamster proteins

If you are not sure, talk to your healthcare provider before using this medicine.

Tell your healthcare provider if you are pregnant or nursing because ESPEROCT® might not be right for you.

## What should I tell my healthcare provider before I use 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.
- Are pregnant or planning to become pregnant.
- Have been told that you have inhibitors to Factor VIII.

## How should I use ESPEROCT®?

Treatment with ESPEROCT® should be started by a healthcare provider who is experienced in the care of patients with hemophilia A.

ESPEROCT® is given as an infusion into the vein.

You may infuse ESPEROCT® at a hemophilia treatment center, at your healthcare provider's office or in your home. You should be trained on how to do infusions by your hemophilia treatment center or healthcare provider. Many people with hemophilia A learn to infuse the medicine by themselves or with the help of a family member.

Your healthcare provider will tell you how much ESPEROCT® to use based on your weight, the severity of your hemophilia A, and where you are bleeding. Your dose will be calculated in international units, IU.

**Call your healthcare provider right away if your bleeding does not stop after taking ESPEROCT®.**

If your bleeding is not adequately controlled, it could be due to the development of Factor VIII inhibitors. This should be checked by your healthcare provider. You might need a higher dose of ESPEROCT® or even a different product to control bleeding. Do not increase the total dose of ESPEROCT® to control your bleeding without consulting your healthcare provider.

## Use in children

ESPEROCT® can be used in children. Your healthcare provider will decide the dose of ESPEROCT® you will receive.

## If you forget to use ESPEROCT®

If you forget a dose, infuse the missed dose when you discover the mistake. Do not infuse a double dose to make up for a forgotten dose. Proceed with the next infusions as scheduled and continue as advised by your healthcare provider.

## If you stop using ESPEROCT®

Do not stop using ESPEROCT® without consulting your healthcare provider.

If you have any further questions on the use of this product, ask your healthcare provider.

## What if I take too much ESPEROCT®?

Always take ESPEROCT® exactly as your healthcare provider has told you. You should check with your healthcare provider if you are not sure. If you infuse more ESPEROCT® than recommended, tell your healthcare provider as soon as possible.

## What are the possible side effects of ESPEROCT®?

**Common Side Effects Include:**

- rash or itching
- swelling, pain, rash or redness at the location of infusion

**Other Possible Side Effects:**

You could have an allergic reaction to coagulation Factor VIII products. **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.

Your body can also make antibodies called "inhibitors" against ESPEROCT®, which may stop ESPEROCT® from working properly. Your healthcare provider may need to test your blood for inhibitors from time to time.

These are not all of the possible side effects from ESPEROCT®. Ask your healthcare provider for more information. You are encouraged to report side effects to FDA at 1-800-FDA-1088.

Tell your healthcare provider about any side effect that bothers you or that does not go away.

## What are the ESPEROCT® dosage strengths?

ESPEROCT® comes in five different dosage strengths. The actual number of international units (IU) of Factor VIII in the vial will be imprinted on the label and on the box. The five different strengths are as follows:

| Cap Color Indicator | Nominal Strength |
|---|---|
| Red | 500 IU per vial |
| Green | 1000 IU per vial |
| Gray | 1500 IU per vial |
| Yellow | 2000 IU per vial |
| Black | 3000 IU per vial |

Always check the actual dosage strength printed on the label to make sure you are using the strength prescribed by your healthcare provider.

## How should I store ESPEROCT®?

**Prior to Reconstitution** (mixing the dry powder in the vial with the diluent):

Protect from light. Do not freeze ESPEROCT®.

ESPEROCT® can be stored in refrigeration at 36°F to 46°F (2°C to 8°C) for up to 30 months until the expiration date stated on the label. During the 30 month shelf life, ESPEROCT® may be kept at room temperature (not to exceed 86°F/30°C) for up to 12 months, **or** up to 104°F (40°C) for no longer than 3 months.

If you choose to store ESPEROCT® at room temperature:

- Record the date when the product was removed from the refrigerator.
- Do not return the product to the refrigerator.
- Do not use after 12 months if stored up to 86°F (30°C) **or** after 3 months if stored up to 104°F (40°C) **or** the expiration date listed on the vial, whichever is earlier.

Do not use this medicine after the expiration date which is on the outer carton and the vial. The expiration date refers to the last day of that month.

**After Reconstitution:**

The reconstituted (the final product once the powder is mixed with the diluent) ESPEROCT® should appear clear and colorless without visible particles.

The reconstituted ESPEROCT® should be used immediately.

If you cannot use the reconstituted ESPEROCT® immediately, it must be used within 4 hours when stored at or below 86ºF (30°C) or within 24 hours when stored in a refrigerator at 36°F to 46°F (2°C to 8°C). Store the reconstituted product in the vial.

Keep this medicine out of the sight and out of reach of children.

## What else should I know about ESPEROCT® and hemophilia A?

Medicines are sometimes prescribed for purposes other than those listed here. Do not use ESPEROCT® for a condition for which it is not prescribed. Do not share ESPEROCT® with other people, even if they have the same symptoms that you have.

Revised: 10/2019

ESPEROCT® is a trademark of Novo Nordisk Health Care AG.

For Patent Information, refer to: http://novonordisk-us.com/patients/products/product-patents.html

**More detailed information is available upon request.** Available by prescription only.

Manufactured by:
Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd, Denmark

For information about ESPEROCT® contact:
Novo Nordisk Inc.
800 Scudders Mill Road
Plainsboro, NJ 08536, USA
1-800-727-6500



US19ESP00168 December 2019

novo nordisk®

# Upcoming Educational Dinners:

Contact Angel DiRuzza at adiruzza@hoii.org to register. Check out our Facebook (@HEMOINDY) page and website calendar for more details on upcoming in person educational dinners!

**Topic:** **Your Time To Thrive: Build an Optimistic Mindset**
**Sponsored by Genentech**
**When:** Thursday, July 8th
**Time:** 6:45pm
**Where:** The District Tap
3720 E 82nd St
Indianapolis, IN 46240

**Topic:** **How to Communicate With Your Child's School**
**Sponsored by Novo Nordisk**
**When:** Thursday, July 20th
**Time:** 6:30pm
**Where:** Location TBD

# Judy Doyle

Patient advocate

## About Judy

Judy is a Novo Nordisk Hemophilia Community Liaison with 18 years of experience supporting those with bleeding disorders. She loves the passion of the hemophilia community to get things done and not let things stand in their way.

## Hemophilia Community Liaison

OH, IN

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novo nordisk®

sigilon therapeutics™

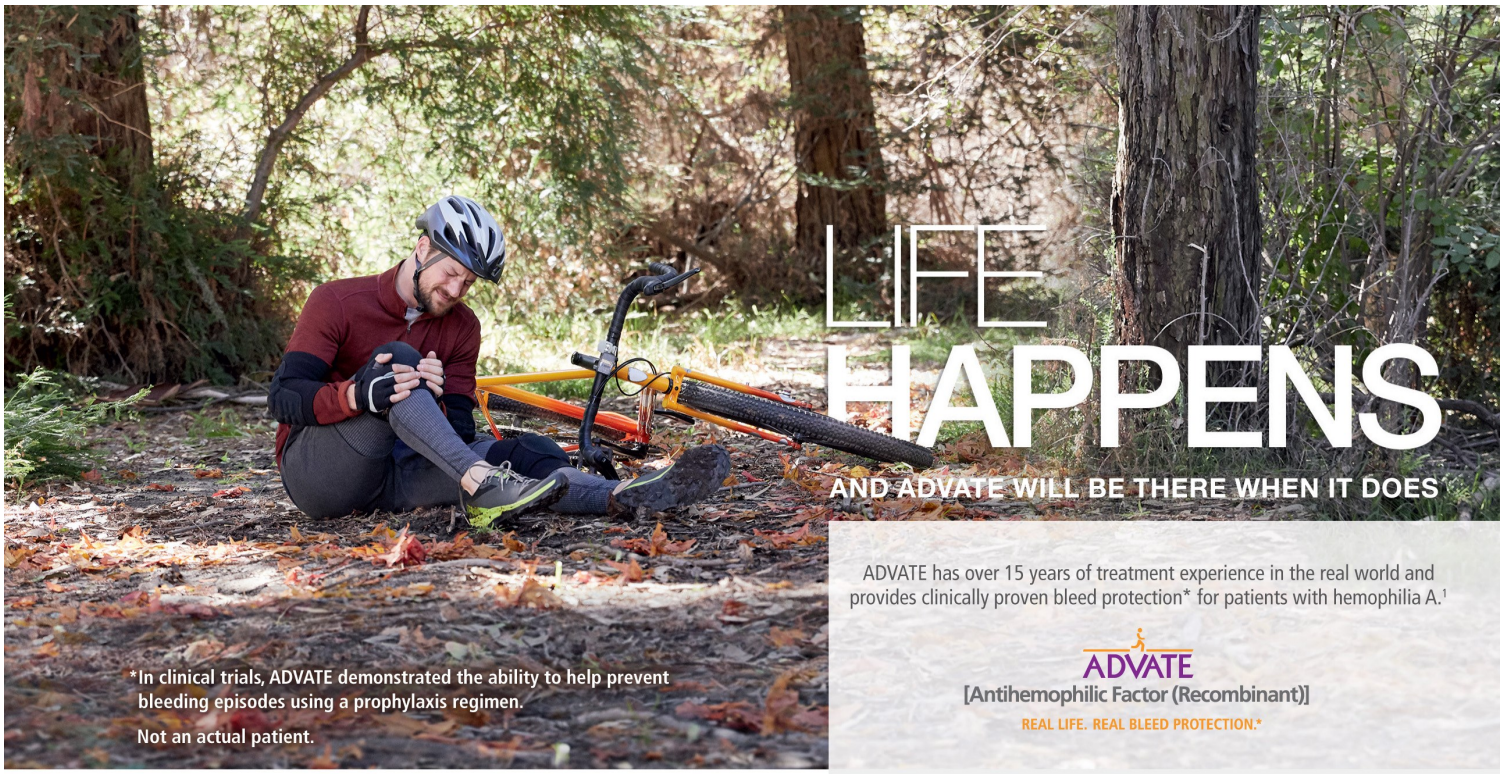
LESS FEAR, MORE HOPE

**Sigilon is developing potential functional cures for chronic diseases through its Shielded Living Therapeutics™ platform, using non-viral engineered cell-based therapies**

**Our areas of focus in rare blood disorders include:**

- **Hemophilia A**
- FVII Deficiency
- Hemophilia B

Here to Listen:
Meet the Patient Advocacy Team




ADVATE has over 15 years of treatment experience in the real world and provides clinically proven bleed protection* for patients with hemophilia A.[1]

ADVATE
[Antihemophilic Factor (Recombinant)]
REAL LIFE. REAL BLEED PROTECTION.*

AdvateRealLife.com

### Prophylaxis with ADVATE prevented bleeds[1]

The ability of ADVATE to treat or prevent bleeds was evaluated in a clinical study using a standard prophylaxis, pharmacokinetic driven prophylaxis, and on-demand treatment.

53 previously treated patients (PTPs) with severe to moderately severe hemophilia A were analyzed. For the first 6 months of the study, patients received on-demand treatment. For the following 12 months of the study, patients received either standard prophylaxis every 48 hours or a pharmacokinetic-driven prophylaxis every 72 hours. The primary goal of the study was to compare annual bleeding rates between those receiving prophylaxis treatment and those receiving treatment on-demand. The number of bleeds per year for the 2 prophylaxis regimens were comparable.

- Those patients experienced a median of 1 overall bleed per year on either prophylaxis treatment vs 44 overall bleeds per year with on-demand treatment.† This represented a 98% reduction in overall bleeds per year.
- Zero bleeds were reported in 42% of patients (22 out of 53 patients) during 12 months on prophylaxis

†Median is the middle number in a group of numbers arranged from lowest to highest.

## ADVATE Important Information

### What is ADVATE?

- ADVATE is a medicine used to replace clotting factor (factor VIII or antihemophilic factor) that is missing in people with hemophilia A (also called "classic" hemophilia).
- ADVATE is used to prevent and control bleeding in adults and children (0-16 years) with hemophilia A. Your healthcare provider (HCP) may give you ADVATE when you have surgery.
- ADVATE can reduce the number of bleeding episodes in adults and children (0-16 years) when used regularly (prophylaxis).

ADVATE is not used to treat von Willebrand disease.

### DETAILED IMPORTANT RISK INFORMATION

### Who should not use ADVATE?

Do not use ADVATE if you:

- Are allergic to mice or hamsters.
- Are allergic to any ingredients in ADVATE.

Tell your HCP if you are pregnant or breastfeeding because ADVATE may not be right for you.

### What should I tell my HCP before using ADVATE?

Tell your HCP if you:

- Have or have had any medical problems.
- Take any medicines, including prescription and non-prescription medicines, such as over-the-counter medicines, supplements or herbal remedies.
- Have any allergies, including allergies to mice or hamsters.
- Are breastfeeding. It is not known if ADVATE passes into your milk and if it can harm your baby.

### What should I tell my HCP before using ADVATE? (continued)

- Are or become pregnant. It is not known if ADVATE may harm your unborn baby.
- Have been told that you have inhibitors to factor VIII (because ADVATE may not work for you).

### What important information do I need to know about ADVATE?

- You can have an allergic reaction to ADVATE. Call your HCP right away and stop treatment if you get a rash or hives, itching, tightness of the throat, chest pain or tightness, difficulty breathing, lightheadedness, dizziness, nausea or fainting.
- Do not attempt to infuse yourself with ADVATE unless you have been taught by your HCP or hemophilia center.

### What else should I know about ADVATE and Hemophilia A?

- Your body may form inhibitors to factor VIII. An inhibitor is part of the body's normal defense system. If you form inhibitors, it may stop ADVATE from working properly. Talk with your HCP to make sure you are carefully monitored with blood tests for the development of inhibitors to factor VIII.

### What are possible side effects of ADVATE?

- Side effects that have been reported with ADVATE include: cough, headache, joint swelling/aching, sore throat, fever, itching, unusual taste, dizziness, hematoma, abdominal pain, hot flashes, swelling of legs, diarrhea, chills, runny nose/congestion, nausea/vomiting, sweating, and rash. Tell your HCP about any side effects that bother you or do not go away or if your bleeding does not stop after taking ADVATE.

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.**

**Please see Important Facts about ADVATE on the following page and discuss with your HCP.**

**For Full Prescribing Information, visit www.ADVATE.com.**

**Reference: 1.** ADVATE Prescribing Information.



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ADVATE
[Antihemophilic Factor (Recombinant)]

# Important facts about

**ADVATE [Antihemophilic Factor (Recombinant)]**

This leaflet summarizes important information about ADVATE. Please read it carefully before using this medicine. This information does not take the place of talking with your healthcare provider, and it does not include all of the important information about ADVATE. If you have any questions after reading this, ask your healthcare provider.

## What is the most important information I need to know about ADVATE?

Do not attempt to do an infusion to yourself unless you have been taught how by your healthcare provider or hemophilia center.

You must carefully follow your healthcare provider's instructions regarding the dose and schedule for infusing ADVATE so that your treatment will work best for you.

## What is ADVATE?

ADVATE is a medicine used to replace clotting factor (factor VIII or antihemophilic factor) that is missing in people with hemophilia A (also called "classic" hemophilia). The product does not contain plasma or albumin. Hemophilia A is an inherited bleeding disorder that prevents blood from clotting normally.

ADVATE is used to prevent and control bleeding in adults and children (0-16 years) with hemophilia A.

Your healthcare provider may give you ADVATE when you have surgery. ADVATE can reduce the number of bleeding episodes in adults and children (0-16 years) when used regularly (prophylaxis).

ADVATE is not used to treat von Willebrand disease.

## Who should not use ADVATE?

You should not use ADVATE if you:

- Are allergic to mice or hamsters.
- Are allergic to any ingredients in ADVATE.

Tell your healthcare provider if you are pregnant or breastfeeding because ADVATE may not be right for you.

## How should I use ADVATE?

ADVATE is given directly into the bloodstream.

You may infuse ADVATE at a hemophilia treatment center, at your healthcare provider's office or in your home. You should be trained on how to do infusions by your healthcare provider or hemophilia treatment center. Many people with hemophilia A learn to infuse their ADVATE by themselves or with the help of a family member.

Your healthcare provider will tell you how much ADVATE to use based on your weight, the severity of your hemophilia A, and where you are bleeding.

You may have to have blood tests done after getting ADVATE to be sure that your blood level of factor VIII is high enough to clot your blood.

Call your healthcare provider right away if your bleeding does not stop after taking ADVATE.

## What should I tell my healthcare provider before I use ADVATE?

You should tell your healthcare provider if you:

- Have or have had any medical problems.
- Take any medicines, including prescription and non-prescription medicines, such as over-the-counter medicines, supplements or herbal remedies.
- Have any allergies, including allergies to mice or hamsters.
- Are breastfeeding. It is not known if ADVATE passes into your milk and if it can harm your baby.
- Are pregnant or planning to become pregnant. It is not known if ADVATE may harm your unborn baby.
- Have been told that you have inhibitors to factor VIII (because ADVATE may not work for you).

## What are the possible side effects of ADVATE?

You can have an allergic reaction to ADVATE.

Call your healthcare provider right away and stop treatment if you get a rash or hives, itching, tightness of the throat, chest pain or tightness, difficulty breathing, lightheadedness, dizziness, nausea or fainting.

Side effects that have been reported with ADVATE include:

| | | |
|---|---|---|
| cough | headache | joint swelling/aching |
| sore throat | fever | itching |
| unusual taste | dizziness | hematoma |
| abdominal pain | hot flashes | swelling of legs |
| diarrhea | chills | runny nose/congestion |
| nausea/vomiting | sweating | rash |

Tell your healthcare provider about any side effects that bother you or do not go away

These are not all the possible side effects with ADVATE. You can ask your healthcare provider for information that is written for healthcare professionals.

## What else should I know about ADVATE and Hemophilia A?

Your body may form inhibitors to factor VIII. An inhibitor is part of the body's normal defense system. If you form inhibitors, it may stop ADVATE from working properly. Consult with your healthcare provider to make sure you are carefully monitored with blood tests for the development of inhibitors to factor VIII.

Medicines are sometimes prescribed for purposes other than those listed here. Do not use ADVATE for a condition for which it is not prescribed. Do not share ADVATE with other people, even if they have the same symptoms that you have.

**The risk information provided here is not comprehensive. To learn more, talk with your health care provider or pharmacist about ADVATE. The FDA-approved product labeling can be found at www.ADVATE.com or 1-877-825-3327.**

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.**



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HEMOPHILIA OF INDIANA

6910 N. Shadeland Ave., Suite 140
Indianapolis, IN 46220
www.hoii.org
(317) 570-0039



*The material provided in Vital Link is only for general information purposes. HoII does not give medical advice or engage in the practice of medicine. HoII recommends in all cases that you consult your physician or HTC before pursuing any course of treatment.

## Mark your Calendars!

- Hearts for Hemophilia Gala - July 30th
- HoII Annual Meeting - August 14th & 15th
- UNITE for Bleeding Disorders Walk - August 21st

Call our office @ (317) 570-0039 or email Kristy McConnell @ kmcconnell@hoii.org if you would like to get involved in any of our events!

- Check out our social media pages for updates!!!