Vital Link



...For Hoosiers Living with a Bleeding Disorder

July 2019

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Camp Brave Eagle was started in 1999 by Dr. Amy Shapiro, Medical Director of the Indiana Hemophila and Thrombosis Center. It is a wonderful opportunity for children with bleeding disorders and their siblings to participate in a traditional summer camp experience. The camp encourages selfsufficiency, builds confidence, increases campers' self esteem, and promotes a positive outlook! This years Camp hosted a record number of 140 campers! The campers were busy from sun up to sun down with kayaking, swimming, canoeing, arts & crafts, fishing, and so much more! In addition to the fun activities, all campers (both those affected by a bleeding disorders and their siblings) are given the opportunity to earn their "Big Stick" by learning how to self infuse from the IHTC! Hemophilia of Indiana would like to say a very special thank you to all of our Sponsors and donors that make it possible to provide such an incredible experience to our campers!! Hemophilia of Indiana is focused on using all donations wisely, stretching donation and grant dollars to their fullest extent!



































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myPKFiT™ for ADVATE® Mobile App

[Antihemophilic Factor (Recombinant)]

The FIRST AND ONLY FDA-approved mobile app for PK dosing in patients with hemophilia A*¹



*Ages 16 and older

Antihemophilic Factor

(Recombinant)]

Personalize and track your ADVATE treatment²

Matthew ~

FACTOR METER

100

Bleed Track



The myPKFiT mobile app is intended only for eligible patients taking ADVATE who have discussed a personalized ADVATE treatment plan with their healthcare professional. Your doctor may use the myPKFiT software to help analyze your ADVATE treatment data and pharmacokinetic (PK) profile, and more, in real time.²⁻⁴

Factor in personalized treatment at ADVATE.com

Talk to your doctor about myPKFiT and your ADVATE treatment.

You can then download it from the App Store or Google Play: Available for iOS 10 and 11 and Android 6 and 7 **Note:** Activation requires a valid QR code from your doctor

myPKFiT™ for ADVATE Patients Mobile Application Intended Use

- The myPKFiT for Patients Mobile Application ("myPKFiT Mobile App") is intended for use by patients with hemophilia A being treated with ADVATE [Antihemophilic Factor (Recombinant)] who are 16 years of age or older with a body weight of 45 kg or higher, and their caregivers.
- The myPKFiT Mobile App is designed to make it convenient for you to record your infusion and bleed events, track your estimated Factor VIII levels following a prophylactic infusion, and export the data for review by your health care provider ("HCP").
- Your HCP can use the myPKFiT software to generate ADVATE dosage amount and frequency recommendations for routine prophylaxis using your age, body weight information, and laboratory tests that measure your Factor VIII clotting activity. Using myPKFiT software, HCPs can evaluate various prophylaxis dose regimens tailored to your individual needs and treatment plan.
- myPKFiT Mobile App should only be used by hemophilia A patients treated with ADVATE, as per the ADVATE Prescribing Information.
- myPKFiT Mobile App is not indicated for use by patients with von Willebrand disease. myPKFiT Mobile App should not be used by patients who have developed inhibitors to Factor VIII products.

myPKFiT for Patients Mobile Application is Rx only. For safe and proper use of the myPKFiT Mobile App, please refer to the complete instructions for use in the User Manual.

ADVATE [Antihemophilic Factor (Recombinant)] 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.
- 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.

Learn more at www.ADVATE.com

References: 1. Data on file: Takeda Pharmaceutical Company Limited, Lexington, MA 02421. **2.** myPKFiT for Healthcare Professionals v3.1 User Manual. 2018. **3.** Björkman S. Limited blood sampling for pharmacokinetic dose tailoring of FVIII in the prophylactic treatment of haemophilia A. *Haemophilia*. 2010;16(4):597-605. **4.** Álvarez-Román MT, Fernandez-Bello I, de la Corte-Rodríguez H, et al. Experience of tailoring prophylaxis using factor VIII pharmacokinetic parameters estimated with myPKFiT in patients with severe haemophilia A without inhibitors. *Haemophilia*. 2017;23(1):e50-e54.

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Study confirms Hoosiers living with blood disorders benefit from Hemophilia Treatment Center's direct care

Less visits to the ER, better compliance with preventing complications, and the ability to self-administer medication are some of the benefits experienced more by Hoosiers who seek bleeding disorder treatment at a Hemophilia Treatment Center (HTC) than those who go elsewhere—this, despite these patients being more likely to have severe hemophilia.

These significant findings and more can be found in the complete Indiana-focused study, entitled "Population-based surveillance of haemophilia and patient outcomes in Indiana using multiple data sources." Modeled after the influential epidemiological surveillance project conducted by the Centers for Disease Control and Prevention (CDC) in the late 1990s, this paper was recently published in the international journal Haemophilia and describes key findings from the Indiana Hemophilia Surveillance Project (IHSP).



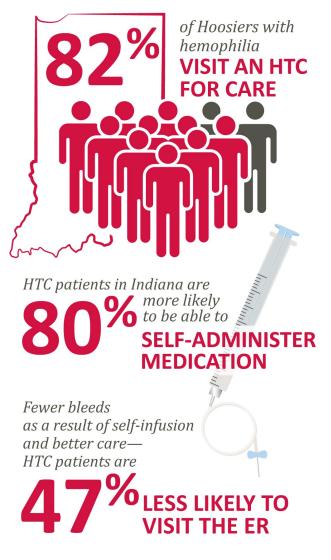
HTCs are health care centers that specialize in the comprehensive care of rare and complex bleeding disorders.

To receive a federal designation as an HTC, facilities must demonstrate deep expertise for treating these complex conditions. Indiana Hemophilia & Thrombosis Center (IHTC) is Indiana's only federally–designated Hemophilia Treatment Center.

The new study involved analyzing de-identified medical records to determine diagnoses of hemophilia and treatment sought within the state. The severity of each patient's hemophilia was noted, as well as where they sought care, how often, and why.

"The findings support the high quality of care provided by the federally recognized network of HTCs across the country, particularly in Indiana," said Dr. Amy Shapiro, IHSP member and co-founder of IHTC. "This study re-enforces the messaging of HTCs, the CDC, and the National Hemophilia Foundation for the past 20 years – if you're not being seen at an HTC, you're not receiving the best care."

What's more, the IHSP found that more hemophilia patients in Indiana are being cared for at an HTC compared to 20 years ago.



"What the study found is hemophilia is more common in Indiana and is likely more common throughout the U.S. than it was 20 years ago," explained Chris Roberson, IHSP member and Director of Compliance & Community Programs for IHTC. "This is also likely because care has improved, so patients are living longer and then having more children."

Despite those patients with hemophilia seeking care at an HTC usually having a more severe form of the disease, they have better outcomes. Patients are 47% less likely to visit the emergency room, and they are more likely to be able to self-administer their medication to prevent bleeding, rather than only taking it after they've experienced a bleed.

Is Your Smartphone Disrupting Your Sleep?

A good night's rest is key to managing a bleeding disorder, but evidence shows using a phone before bed can negatively affect sleep and thus hurt your health Author: Lisa Fields

Taking Charge

Does this scenario sound familiar? It's late and you should be going to bed, but you have a few more e-mails to read or social media posts to catch up on. So you grab your smartphone, tablet or laptop and scroll away before turning in.

It might sound like a harmless habit, but the intrusion of technological devices into our bedrooms is taking a toll on our sleep quality, which in turn, studies show, increases our risk for several health problems.

Reasons why you need a good night's rest

Alongside other pillars of good health like proper nutrition and exercise, sleep is critical to one's overall well-being. And for people with bleeding disorders, too little sleep is of particular concern.

"Living with a chronic illness means you really need to take care of fundamentals, like sleep," says Kerry Hansen, RN, a nurse clinician at the Center for Bleeding and Clotting Disorders at the University of Minnesota and a member of the National Hemophilia Foundation's (NHF) Nursing Working Group.

The Centers for Disease Control and Prevention recommends adults get at least seven hours of slumber nightly. But a 2016 CDC study found 1 in 3 Americans fail to regularly hit that mark, putting them at greater risk for chronic conditions including diabetes, heart disease, anxiety and depression.

There are also specific reasons why it's good for people with bleeding disorders to mind their sleep hygiene.

"Getting too little sleep can cause you to gain weight, which puts more stress on weightbearing joints," Hansen says. "And considering that joint bleeds are the most common type of bleed in hemophilia, keeping weight under control is important." Hansen also notes that sleep-deprived people are more prone to accidents and falls, and there's a strong link between sleep deprivation and anxiety and depression, especially in people with chronic health issues. "Depression among people with bleeding disorders is higher than the average population," Hansen says. "Something as simple as sleep can really help all these different issues."

Sleep thieves

You probably know that consuming caffeine later in the day, eating a large meal near bedtime and drinking alcohol can disturb sleep quality. But that habit of using your smartphone or tablet before hitting the hay is also a problem. According to research, such activity affects sleep in two ways:

First, device screens emit blue light wavelengths that mimic daylight. Such light tricks your body into thinking it shouldn't be ready for bed and it suppresses release of the sleep-signaling hormone melatonin.

"Melatonin is a biological marker of when you're going to get sleepy," says Brett Kuhn, PhD, a psychologist and certified behavioral sleep medicine specialist at the Munroe-Meyer Institute for Genetics & Rehabilitation and University of Nebraska Medical Center. "Anytime that you're getting nighttime blue light exposure it's going to delay your melatonin onset and delay the time that you fall asleep."

Second, smartphones and tablets are incredibly engaging and keep the mind buzzing, making it difficult to put them down. "This second issue is the bigger issue," Kuhn says. "It's a very stimulating, interesting activity that is preventing us from going to bed when we're tired."

Take back the bedroom

As hard as it might be to put away your devices and disconnect, doing so is crucial to a good night's rest. "Between 30 and 60 minutes before bed, you have to get away from technology and go through a bedtime routine," Kuhn says.

Along with setting a device curfew, that routine should include ensuring your bedroom is quiet, dark, cool and relaxing. "Try to create a peaceful environment," advises Cynthia Nichols, PhD, a board-certified sleep specialist at Munson Medical Center in Traverse City, Michigan. "You don't have to spend three hours getting ready for bed, but try to protect that half hour or so before going to sleep to give yourself time to wind down."

3 ways tech can improve sleep and help you get more rest

While looking at device screens near bedtime is a no-no, not all technology disrupts slumber. The following devices may help you snooze better:

Phototherapy light

• A light therapy device, typically used in the morning, helps regulate the body's sleep rhythm, which helps you sleep deeper. There are light boxes you sit in front of and wearable devices such as a visor or special glasses that beam light gently into the eyes.

White noise machines

• These small, inexpensive devices provide soothing, steady background noise that can

drown out a partner's snoring or other sounds that might disrupt sleep. A fan can provide a similar effect.

Dawn simulators

• For people who prefer to be roused from their slumber more slowly, these bedside table lights are an alternative to a jarring alarm. The light gradually illuminates your bedroom as if you're waking up with the sunrise.

Note: Sleep specialist Cynthia Nichols, PhD, says a light therapy device should deliver a minimum of 10,000 lux at whatever distance the product recommends you sit from it.

Tips on better sleep

• <u>A Good Night's Sleep</u> (National Institute on Aging)

• <u>Brain Basics: Understanding Sleep</u> (National Institute of Neurological Disorders and Stroke)

• <u>5 Things To Know About Sleep Disorders and Complementary Health</u> <u>Approaches</u> (National Center for Complementary and Integrative Health)

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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. Carefully follow your healthcare provider's instructions regarding when to use an on-demand bypassing agent or factor VIII, and the dose and schedule to use for breakthrough bleed treatment. HEMLIBRA may cause serious side effects when used with activated prothrombin complex concentrate (aPCC; FEIBA®), including thrombotic microangiopathy (TMA), and blood clots (thrombotic events). 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.

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



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

- stomach (abdomen)
- or back pain
- swelling of arms and legs
- nausea or vomiting
- yellowing of skin and eyes
- 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

- cough up blood - feel faint
- headache
 - numbness in your face
- chest pain or tightness
- shortness of breath - fast heart rate
- 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.

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Doug Thompson Teen Leadership Camp

Doug Thompson Teen Leadership Camp (DTTLC) is a leadership camp for teen boys with bleeding disorders ages 14-18. (99% of people with hemophilia are male.) DTTLC was created in memory of beloved mentor, colleague, and friend within the bleeding disorders community., Doug Thompson. Doug had a passion for teens and enjoyed working with them during the impressionable years of life. The Doug Thompson Teen Leadership Camp Program was designed to provide teen members of the bleeding disorder community the opportunity to develop and refine life skills while participating in an adventure camp experience. Each year 10 teen "leaders" are chosen to participate in the teen leadership program. DTTLC has four main goals: To develop self-confidence through challenging activities, to prepare participants to be responsible about their health condition as adults through education and by completing steps necessary to pursue college admission, to develop their innate ability through reasonable risk-taking through physical activities, and to foster relationships and build a sense of community between young people with bleeding disorders. This year's Doug Thompson Teen Leadership Camp ventured to Hocking Hills State Park in Ohio and participated in a variety of activities including hiking, rock climbing, tubing, and even a "Chopped" food challenge! The campers and counselors had an incredible week of new adventures and building life long friendships.













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antihemophilic factor (recombinant) PEGylated-aucl

LET'S GO





SAVE THE DATE!

Participate. Volunteer. Donate.

Date: Saturday, September 21, 2019 Registration Check-In Time: 8:30am Walk Start Time: 10:30am Distance: 3 miles & 1 mile routes Location: Fort Harrison State Park Address: 6000 N. Post Rd., Indianapolis, IN 46216

Join us to support the Unite for Bleeding Disorders Walk! We will walk to raise critical FUNDS and AWARENESS for the bleeding disorders community. Your support is greatly appreciated! There will be exhibit booths, a Kid's Zone, and fun for the whole family!

To register, go to <u>www.hemophilia.org/walk</u>, select IN-Indianapolis, click "Create a Team" or "Join a Team."

CONTACT US

For more information, please visit <u>www.hemophilia.org/walk</u> or contact: Kristy McConnell, Local Walk Manager, at 317-570-0039 or <u>kmcconnell@hoii.org</u>



Upcoming Educational Dinners:

Contact Angel Couch at acouch@hoii.org to register. Check out our Facebook (@HEMOINDY) page and website for details on educational dinners!

Indianapolis, IN

Topic: Topic TBD Presented by Pfizer
When: August 13, 2019
Time: 6:00pm
Where: Restaurant Location TBD





2019 Annual Meeting

August 10th & August 11th

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