Vital Link

...For Hoosiers Living with a Bleeding Disorder

HEMOPHILIA OF INDIANA

March 2021

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

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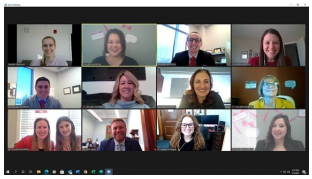
Virtual Washington Days 2021

Every year staff from Hemophilia of Indiana and the Indiana Thrombosis Center and members of the bleeding disorders community attend Washington Days in Washington DC. Washington Days provides an opportunity to meet with US House of Representatives and the Senate to advocate on behalf of the bleeding disorders community in Indiana. Due to the current pandemic, this year's event was switched to a virtual platform. Even with the virtual platform, the 2021 Washington Days was a very successful day of meetings. Our Indiana group was fortunate enough to meet with Members and their staff from Congressmen Hollingsworth and Banks, Congresswomen Spartz and Walorski, and Senator's Braun and Young. In 2020, thanks to incredible advocacy efforts, the Hemophilia SNF Access Act (HR 133, The Consolidated Appropriations Act) was passed on December 21, 2020. This critical legislation will rectify a long-standing problem to improve access to skilled nursing facilities (SNFs) for Medicare beneficiaries with hemophilia and other bleeding disorders. NHF has heard from many community members over the years about challenges accessing SNF facilities due to the way that Medicare reimburses bleeding disorders treatments. The advocacy doesn't stop with the passing of this Act. Private insurance companies have started to implement Copay Accumulator Adjustor Programs. This programs disallow co-pay assistance from counting towards a patient's out of pocket maximum. The medication taken by people with bleeding disorders is very expensive resulting in a high copay. Many patients need co-pay assistance programs to help them afford their high out of pocket costs. When copay assistance is not allowed, many patients cannot afford their treatment and stop taking them or reduce the prescribed dosage which can lead to unintended consequences such as increased ER visits, joint bleeds/damage, and missed days from work and/or school. All insurance plans should be required to count all co-pays (regardless of who pays) towards a person's OOP maximum The ask to our members of the House of Representatives was so support a letter that is in the House urging Present Biden to prohibit accumulator adjustor programs. The ask to our Senate members was to consider writing a similar letter and/or legislation. The Members and their staff were very receptive which made for positive and interactive meetings. We still need help from community members and supporters of the bleeding disorders community. You can contact your House of Representative and Senators and ask them to help support this important initiative. For more information to register to vote or find your elected official go to Hemophilia.org under the Advocacy tab!



Upcoming Virtual 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 virtual educational dinners!

Topic: **The Road To Independence: Being A Teen or Young Adult with Hemophilia**
Sponsored by Pfizer
When: Tuesday, March 16th
Time: 6:30pm - 7:30pm

Topic: **Food and Fitness Basics**
sponsored by Novo Nordisk
When: Thursday, April 8th
Time: 6:30pm - 7:30pm

Topic: **Tai Chi Tuesday**.
An interactive virtual Tai Chi lesson in the Comfort of your own home! Sponsored by CSL Behring
When: Tuesday, April 20th
Time: 6:30pm - 7:30pm

Topic: **Supporting Emerging Skills**
Sponsored by Sanofi Genzyme.
When: Tuesday, May 18th
Time: 6:30pm - 7:30pm

Indiana Hemophilia & Thrombosis Center

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.

Pediatric Hematologists
Adult Hematologists
Nurse Practitioners
Physician Assistants
Nurses
Physical Therapists
Dental Hygienists
Pharmacy Team
Psychologist
Genetic Counselor
Research
Social Workers
Registered Dietician
Career & School Counselors
Patient Insurance Coordinators
Child Life Specialist






Indiana's only Center of Excellence for bleeding & clotting disorders

The state's only federally-designated Hemophilia Treatment Center and the first HTC in the U.S. to receive national medical home certification

Certified as a Medical Home by AAAHC Accreditation Association for Ambulatory Health Care, Inc.

ACHC Accredited

Anticoagulation Center of Excellence

8326 Naab Road · Indianapolis, IN 46260 · 317.871.0000 · www.ihtc.org

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.

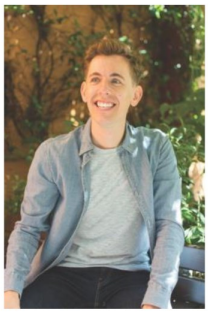
Manufactured by: Genentech, Inc., A Member of the Roche Group,
1 DNA Way, South San Francisco, CA 94080-4990
U.S. License No. 1048

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

Patient Education Through Social Media in the COVID Era

Laurence Woollard



Laurence Woollard: Hemophilia influencer

The unparalleled, seismic societal shifts over the past year have made many of us readjust in ways we'd never imagined. As I write this, here in the United Kingdom we are facing yet another national lockdown. Strict physical distancing has meant that people are using digital social networks to interact and share information on a historic, extraordinary scale. According to We Are Social, by October 2020, the number of people using social media worldwide surpassed the 4 billion milestone, with an average of 2 million new users joining every day.[1]

While the environment created by the pandemic has bred many falsehoods on social media from so-called armchair epidemiologists, the rise in online traffic from housebound, captive audiences has also inspired more entrepreneurial hustle. Social media is unique; it places people at the center of a vast network, and shifts power by allowing anyone to become an "influencer." This relatively new phenomenon has grown with the mania for online video content, and YouTube is the dominant platform. YouTube influencers, through their informality and authenticity, can be seen as models for observational learning: they have the potential to guide or change the beliefs of their followers. One of the standout "heroes" during the pandemic was Joe Wicks, known as "The Body Coach," who had over 75 million views globally of his daily "PE with Joe" fitness sessions on YouTube.

For many people in the bleeding disorder community under lockdown, decreased physical activity may have negatively impacted their joints and muscles.[2] In response, patient advocacy groups have been forced to adopt and improve virtual operations and e-learning approaches using social media to promote their members' well-being. For example, the European Haemophilia Consortium (EHC) hosted its physical activity campaign #thisway through monthly Facebook live sessions with a specialist physiotherapist.

Social distancing has put a strain on the mental health of many individuals. For young adults in particular, the World Health Organization (WHO) has suggested that staying connected with peers through social media can help them remain positive and challenge mental health stigma. The explosion in popularity of the entertainment-based platform TikTok—with over 30 million monthly users in the US alone—has demonstrated the potential not only to convey important health information, but to address these aspects of the pandemic as well.[3]

Even pre-COVID, more and more people were using social media to gain knowledge and share their health experiences.4 As a result, social media has been promoted as an inexpensive means for patient education, to enable and empower consumers in their health and healthcare-related interactions.[4,5,6] This is particularly significant for people living with chronic conditions, where management and care can be self-guided, fostered through online peer-to-peer interaction and validation, or assisted by a facilitator or healthcare professional.4 The number of physicians involved with hemophilia on social media in a professional capacity is increasing, championed by the likes of Professor Mike Makris in Sheffield, UK, who has become an

influencer in his own right. Professor Makris believes, “Information is no longer a privilege and the time when patients are more up to date and better informed than their doctors is already here.”[7]

Feeling empowered in decision-making about one’s health can play an important role in supporting people as they seek positive health behavior and lifestyle change. Yet, a high level of patient participation and engagement is essential. Preliminary studies have shown that social media interventions lead to some positive effects on the health of people living with chronic diseases, including promoting self-care and self-confidence, as well as offering psychosocial benefits, but these results are limited.[4,6] Similarly, the reporting in hemophilia is scarce, although a recent attempt was made to increase awareness of von Willebrand disease by targeting women in their reproductive years on social media, and inviting them to participate in an online self-assessment tool to recognize abnormal bleeding symptoms.[8]

Although social media is now viewed as a universal communication channel, there is a risk of reducing health information access for those who are not technologically connected. About 22% of the UK’s population lack basic digital skills,[9] and 31% of rural US households are still without access to broadband internet.[10] The pandemic stands to make the impacts of digital exclusion worse for the millions of people affected, and the socioeconomic disadvantaged will be hit the hardest. What’s more, engaging with eHealth (for example, health information from electronic sources) requires a skill set, or literacy, of its own to appraise and apply the knowledge gained in addressing and solving a health problem.[4]

Providers who design social media interventions or campaigns must be mindful of the different population segments in the patient community to ensure equity of access to educational opportunities, and not just target those who are more socially mobile and tech- and eHealth-literate. There is also still a strong need to examine not only how to tailor and deliver more effective and responsive patient education through social media, but also how to assess its impact on patient health outcomes, especially in the “new normal.”

Laurence Woollard is founder and director of On The Pulse, an independent consultancy partnering with global healthcare providers and multi-agencies to drive patient education and choice in hemophilia and rare diseases. Laurence has hemophilia and can be reached at @TheWoollard on Twitter.

1. *We Are Social*, Digital 2020 (2020), datareportal.com/reports/digital-2020-october-global-statshot 2. H. De la Corte-Rodriguez, et al., “What COVID-19 Can Mean for People with Hemophilia Beyond the Infection Risk,” *Expert Review of Hematology* 13, no. 10 (2020): 1073–79. 3. C. H. Basch, et al., “COVID-19 on TikTok: Harnessing an Emerging Social Media Platform to Convey Important Public Health Messages,” *International Journal of Adolescent Medicine and Health*, Aug. 10, 2020. 4. L. Zhou, et al., “Harnessing Social Media for Health Information Management,” *Electronic Commerce Research and Applications* 27 (2018): 139–51. 5. M. Stellefson, et al., “Evolving Role of Social Media in Health Promotion: Updated Responsibilities for Health Education Specialists,” *International Journal of Environmental Research Public Health* 17, no. 4 (2020): 1153. 6. H. Korda, et al., “Harnessing Social Media for Health Promotion and Behavior Change,” *Health Promotion Practice* 14 (2013): 15–23. 7. M. Makris, “Twitter and Haemophilia,” *Haemophilia* 26, no. 2 (2020): 181–82. 8. E. Reynen, et al., “Let’s Talk Period! Preliminary Results of an Online Bleeding Awareness Knowledge Translation Project and Bleeding Assessment Tool Promoted on Social Media,” *Haemophilia* 23 (2017): e282–86. 9. H. Holmes, et al., “‘Pay the Wi-fi or Feed the Children’: Coronavirus Has Intensified the UK’s Digital Divide,” University of Cambridge (2020), www.cam.ac.uk/stories/digitaldivide 10. A. Ramsetty, et al., “Impact of the Digital Divide in the Age of COVID-19,” *Journal of the American Medical Informatics Association* 27, no. 7 (2020): 1147–48.

At Pfizer Hemophilia, we have always been deeply committed to you and to listening to what you have to say. Over the years, what you've shared with us has proven invaluable. The events we sponsor, the technology we develop, and the educational materials we create are all designed in response to the requests, needs, and desires of the hemophilia community.

We are grateful for having the chance to partner with you.

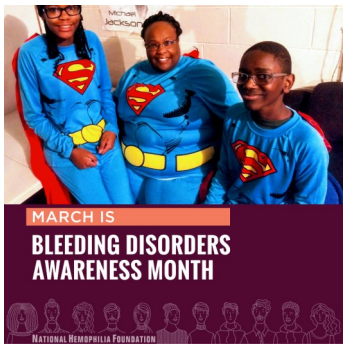
—Your Pfizer Hemophilia Team

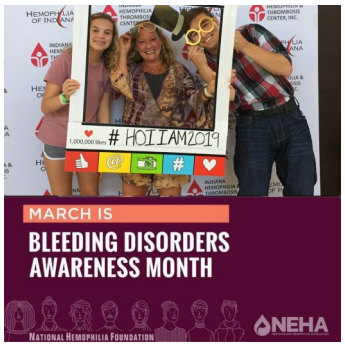
PP-HEM-USA-1120-01

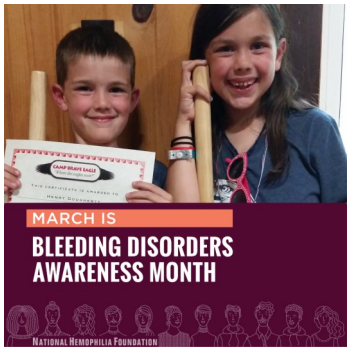
Printed in USA/November 2018

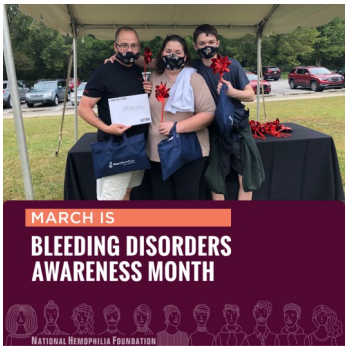
Bleeding Disorders Awareness Month!!!!

Bleeding Disorders Awareness month is celebrated throughout the month of March! All month long, Hemophilia of Indiana will be celebrating the incredible bleeding disorders community of Indiana. There are between 30,000 - 33,000 people living with hemophilia in the US. Von Willebrand Disease (VWD) is the most common bleeding disorder and affects approximately 1 in every 100 people. Hemophilia of Indiana supports approximately 1500 patients and their families throughout the State of Indiana. We offer a variety of educational programs, advocacy programs, support groups, summer camps, and much more! Our Emergency Financial Assistance program was a vital program for our patients and families throughout the current COVID-19 pandemic. Check out our social media pages (@HEMOINDY) for more fun facts and celebrating our community.









How can you help the bleeding disorders community of Indiana???

Go to www.hoii.org/donate to make a donation!!

How to Make Your Home Office More Ergonomic

With the right office equipment, working from home can be just as comfortable and productive as your previous office environment

Author: Michael Hickey

Pain Management

With a full year of working from home under our belts, it's painfully clear as we hunch over our laptops at the kitchen table that working from home can be far from comfortable. For people with bleeding disorders, poor posture can be especially troublesome, adding pain and weakness to joints that might already have recurrent bleeds.

But there are several ways to spruce up your home office so that you're comfortable and productive, and many companies today are reimbursing their employees for home office expenses. Here's how to upgrade your home working environment to be more ergonomic.

Get an Ergonomic Chair

Sitting in a rigid, uncomfortable chair or one without any support for at least eight hours a day won't do your body any favors, so don't settle for a folding chair or a couch. Use an ergonomic chair, which is designed to support proper posture with an adjustable seat height, a headrest, armrests and a curved back for lumbar support.

Consider an Adjustable Standing Desk

Sitting too much can pose health hazards, including back pain and an increased risk of diabetes. So give yourself a chance to stretch your legs and get up, even as you keep working. Plus, there are potential health benefits to stand-up desks, such as improved mood and energy levels.

Use a Laptop Stand or Second Monitor

It's more than likely that you just plop your laptop on your desk and look down at it as you use it. But you don't want to crane your neck constantly as you work. Avoid strain by bringing your screen to eye level with a stand or an adjustable monitor.

Get an Active Footrest

These footrests let you rest your feet comfortably or rock them back and forth, which improves blood circulation and promotes the ergonomic practice of active sitting, which encourages people to be in motion even as they sit.

Use a Keyboard Wrist Rest

You're probably typing on your computer almost every second of the workday, so you better make it comfortable. Wrist rests are designed to keep your wrists in a position that reduces tension while you're typing.

Add Soothing Elements

You shouldn't just be *physically* comfortable in your home office; it should be a space where you feel at ease mentally, so add soothing and productivity-boosting touches to your workspace. Start by bringing in as much natural light as you can, and put a few plants around the room—your productivity might go up after you do. For an added touch of relaxation, use calming scents such as lavender or vanilla.

Article originally posted on HEMAWARE: The Bleeding Disorders Magazine

BOB has hemophilia A with inhibitors.

What is NovoSeven® RT?

NovoSeven® RT (coagulation Factor VIIa, recombinant) is an injectable medicine used for:

- Treatment of bleeding and prevention of bleeding for surgeries and procedures in adults and children with hemophilia A or B with inhibitors, congenital Factor VII (FVII) deficiency, and Glanzmann's thrombasthenia with a decreased or absent response to platelet transfusions
- Treatment of bleeding and prevention of bleeding for surgeries and procedures in adults with acquired hemophilia

Important Safety Information

What is the most important information I should know about NovoSeven® RT?

NovoSeven® RT may cause serious side effects, including:

- **Serious blood clots** that form in veins and arteries with the use of NovoSeven® RT have been reported
- Your healthcare provider should discuss the risks and explain the signs and symptoms of blood clots to you. Some signs of a blood clot may include pain, swelling, warmth, redness, or a lump in your legs or arms, chest pain, shortness of breath, or sudden severe headache and/or loss of consciousness or function
- Your healthcare provider should monitor you for blood clots during treatment with NovoSeven® RT
- You should not use NovoSeven® RT if you have ever had allergic (hypersensitivity) reactions, including severe, whole body reactions (anaphylaxis) to NovoSeven® RT, any of its ingredients, or mice, hamsters, or cows. Signs of allergic reaction include shortness of breath, rash, itching (pruritus), redness of the skin (erythema), or fainting/dizziness

novo nordisk®

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

 Printed in the U.S.A. US18NSVN00126 January 2019

In hemophilia with inhibitors,

Bleeds happen:

Take control with NovoSeven® RT

Controlling bleeds, whenever they happen

- Proven effective to treat hemophilia A or B with inhibitors, at home and in the hospital

Safety supported by clinical trial data

- Low rate (0.2%) of blood clots[a]

Speed when it's needed

- Fast to mix, fast to infuse, and fast to control bleeds[b]

NovoSeven® RT—committed to your experience

- More than 30 years of research and long-term clinical experience[c]

[a]For people with hemophilia A or B with inhibitors.
[b]Administer as a slow bolus injection over 2-5 minutes, depending on the dose administered.
[c]Compassionate use, also known as expanded access, began enrolling in 1988; FDA approval received in 1999.

Visit NovoSevenRT.com today to learn more

What should I tell my healthcare provider before using NovoSeven® RT?

- Tell your healthcare provider if you have any of the following, as these may increase your risk of blood clots:
  - congenital hemophilia and are also receiving treatment with aPCCs (activated prothrombin complex concentrates)
  - are an older patient particularly with acquired hemophilia and receiving other agents to stop bleeding
  - history of heart or blood vessel diseases
- Tell your healthcare provider and pharmacist about all the medicines you take, including all prescription and non-prescription medicines, such as over-the-counter medicines, supplements, or herbal remedies

What are the possible side effects of NovoSeven® RT?

- The most common and serious side effects are blood clots
- Tell your healthcare provider about any side effects that bother you or do not go away, and seek medical help right away if you have signs of a blood clot or allergic reaction

Please see Brief Summary of Prescribing Information on the following pages.

NovoSeven® RT
Coagulation Factor VIIa (Recombinant)

NOVOSEVEN® RT
Coagulation Factor VIIa (Recombinant)

Rx only

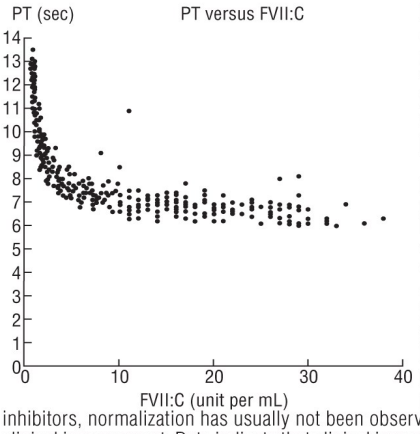
BRIEF SUMMARY. Please consult package insert for full prescribing information.

WARNING: THROMBOSIS: Serious arterial and venous thrombotic events following administration of NOVOSEVEN® RT have been reported. *[See Warnings and Precautions]* Discuss the risks and explain the signs and symptoms of thrombotic and thromboembolic events to patients who will receive NOVOSEVEN® RT. *[See Warnings and Precautions]* Monitor patients for signs or symptoms of activation of the coagulation system and for thrombosis. *[See Warnings and Precautions]*

INDICATIONS AND USAGE: NOVOSEVEN® RT, Coagulation Factor VIIa (Recombinant), is indicated for: Treatment of bleeding episodes and peri-operative management in adults and children with hemophilia A or B with inhibitors, congenital Factor VII (FVII) deficiency, and Glanzmann's thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets; Treatment of bleeding episodes and peri-operative management in adults with acquired hemophilia.

CONTRAINDICATIONS: None known.

WARNINGS AND PRECAUTIONS: Thrombosis: Serious arterial and venous thrombotic events have been reported in clinical trials and postmarketing surveillance. Patients with congenital hemophilia receiving concomitant treatment with aPCCs (activated prothrombin complex concentrates), older patients particularly with acquired hemophilia and receiving other hemostatic agents, or patients with a history of cardiac, vascular disease or predisposed to thrombotic events may have an increased risk of developing thrombotic events *[See Adverse Reactions and Drug Interactions]*. Monitor patients who receive NOVOSEVEN® RT for development of signs or symptoms of activation of the coagulation system or thrombosis. When there is laboratory confirmation of intravascular coagulation or presence of clinical thrombosis, reduce the dose of NOVOSEVEN® RT or stop the treatment, depending on the patient's condition. **Hypersensitivity Reactions:** Hypersensitivity reactions, including anaphylaxis, can occur with NOVOSEVEN® RT. Patients with a known hypersensitivity to mouse, hamster, or bovine proteins may be at a higher risk of hypersensitivity reactions. Discontinue infusion and administer appropriate treatment when hypersensitivity reactions occur. **Antibody Formation in Factor VII Deficient Patients:** Factor VII deficient patients should be monitored for prothrombin time (PT) and factor VII coagulant activity before and after administration of NOVOSEVEN® RT. If the factor VIIa activity fails to reach the expected level, or prothrombin time is not corrected, or bleeding is not controlled after treatment with the recommended doses, antibody formation may be suspected and analysis for antibodies should be performed. **Laboratory Tests:** Laboratory coagulation parameters (PT/INR, aPTT, FVII:C) have shown no direct correlation to achieving hemostasis. Assays of prothrombin time (PT/INR), activated partial thromboplastin time (aPTT), and plasma FVII clotting activity (FVII:C), may give different results with different reagents. Treatment with NOVOSEVEN® has been shown to produce the following characteristics: PT: As shown below, in patients with hemophilia A/B with inhibitors, the PT shortened to about a 7-second plateau at a FVII:C level of approximately 5 units per mL. For FVII:C levels > 5 units per mL, there is no further change in PT. The clinical relevance of prothrombin time shortening following NOVOSEVEN® RT administration is unknown.



INR: NOVOSEVEN® has demonstrated the ability to normalize INR. However, INR values have not been shown to directly predict bleeding outcomes, nor has it been possible to demonstrate the impact of NOVOSEVEN® on bleeding times/volume in models of clinically-induced bleeding in healthy volunteers who had received Warfarin, when laboratory parameters (PT/INR, aPTT, thromboelastogram) have normalized. aPTT: While administration of NOVOSEVEN® shortens the prolonged aPTT in hemophilia A/B patients with inhibitors, normalization has usually not been observed in doses shown to induce clinical improvement. Data indicate that clinical improvement was associated with a shortening of aPTT of 15 to 20 seconds. FVIIa:C: FVIIa:C levels were measured two hours after NOVOSEVEN® administration of 35 micrograms per kg body weight and 90 micrograms per kg body weight following two days of dosing at two hour intervals. Average steady state levels were 11 and 28 units per mL for the two dose levels, respectively.

ADVERSE REACTIONS: The most common and serious adverse reactions in clinical trials are thrombotic events. Thrombotic adverse reactions following the administration of NOVOSEVEN® in clinical trials occurred in 4% of patients with acquired hemophilia and 0.2% of bleeding episodes in patients with congenital hemophilia. **Clinical Trials Experience:** Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug product cannot be directly compared to rates in clinical trials of another drug, and may not reflect rates observed in practice. Adverse reactions outlined below have been reported from clinical trials and data collected in registries. Hemophilia A or B Patients with Inhibitors: In two studies for hemophilia A or B patients with inhibitors treated for bleeding episodes (N=298), adverse reactions were reported in ≥2% of the patients that were treated with NOVOSEVEN® for 1,939 bleeding episodes (see Table 3 below).

Table 3: Adverse Reactions Reported in ≥2% of the 298 Patients with Hemophilia A or B with Inhibitors

Body System Reactions	**# of adverse reactions** (n=1,939 treatments)	**# of patients** (n=298 patients)
Body as a whole		
Fever	16	13
Platelets, Bleeding, and Clotting		
Fibrinogen plasma decreased	10	5
Cardiovascular		
Hypertension	9	6

Serious adverse reactions included thrombosis, pain, thrombophlebitis deep, pulmonary embolism, decreased therapeutic response, cerebrovascular disorder, angina pectoris, DIC, anaphylactic shock and abnormal hepatic function. The serious adverse reactions of DIC and therapeutic response decreased had a fatal outcome. In two clinical trials evaluating safety and efficacy of NOVOSEVEN® administration in the perioperative setting in hemophilia A or B patients with inhibitors (N=51), the following serious adverse reactions were reported: acute post-operative hemarthrosis (n=1), internal jugular thrombosis adverse reaction (n=1), decreased therapeutic response (n=4). *Immunogenicity:* There have been no confirmed reports of inhibitory antibodies against NOVOSEVEN® or FVII in patients with congenital hemophilia A or B with alloantibodies. The incidence of antibody formation is dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to NOVOSEVEN® RT with the incidence of antibodies to other products may be misleading. Congenital Factor VII Deficiency: Data collected from the compassionate/emergency use programs, the published literature, a pharmacokinetics study, and the Hemophilia and Thrombosis Research Society (HTRS) registry showed that 75 patients with Factor VII deficiency had received NOVOSEVEN®: 70 patients for 124 bleeding episodes, surgeries, or prophylaxis; 5 patients in the pharmacokinetics trial. The following adverse reactions were reported: intracranial hypertension (n=1), IgG antibody against rFVIIa and FVII (n=1), localized phlebitis (n=1). *Immunogenicity:* In 75 patients with factor FVII deficiency treated with NOVOSEVEN® RT, one patient developed IgG antibody against rFVIIa and FVII. Patients with factor VII deficiency treated with NOVOSEVEN® RT should be monitored for factor VII antibodies. The incidence of antibody formation is dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to NOVOSEVEN® RT with the incidence of antibodies to other products may be misleading. Acquired Hemophilia: Data collected from four compassionate use programs, the HTRS registry, and the published literature showed that 139 patients with acquired hemophilia received NOVOSEVEN® for 204 bleeding episodes, surgeries and traumatic injuries. Of these 139 patients, 6 patients experienced 8 serious adverse reactions. Serious adverse reactions included shock (n=1), cerebrovascular accident (n=1) and thromboembolic events (n=6) which included cerebral artery occlusion, cerebral ischemia, angina pectoris, myocardial infarction, pulmonary embolism and deep vein thrombosis. Three of the serious adverse reactions had a fatal outcome. Glanzmann's Thrombasthenia: Data collected from the Glanzmann's Thrombasthenia Registry (GTR) and the HTRS registry showed that 140 patients with Glanzmann's thrombasthenia received NOVOSEVEN® RT for 518 bleeding episodes, surgeries or traumatic injuries. The following adverse reactions were reported: deep vein thrombosis (n=1), headache (n=2), fever (n=2), nausea (n=1), and dyspnea (n=1). **Post marketing Experience:** Adverse reactions reported during post marketing period were similar in nature to those observed during clinical trials and include reports of thromboembolic adverse events.

DRUG INTERACTIONS: Avoid simultaneous use of activated prothrombin complex concentrates. Do not mix NOVOSEVEN® RT with infusion solutions. Thrombosis may occur if NOVOSEVEN® RT is administered concomitantly with Coagulation Factor XIII. *[See Warnings and Precautions]*

USE IN SPECIFIC POPULATIONS: Pregnancy: Risk Summary: There are no adequate and well-controlled studies using NOVOSEVEN® RT in pregnant women to determine whether there is a drug-associated risk. Treatment of rats and rabbits with NOVOSEVEN® in reproduction studies has been associated with mortality at doses up to 6 mg per kg body weight and 5 mg per kg body weight respectively. At 6 mg per kg body weight in rats, the abortion rate was 0 out of 25 litters; in rabbits at 5 mg per kg body weight, the abortion rate was 2 out of 25 litters. Twenty-three out of 25 female rats given 6 mg per kg body weight of NOVOSEVEN® gave birth successfully, however, two of the 23 litters died during the early period of lactation. No evidence of teratogenicity was observed after dosing with NOVOSEVEN®. In the U.S. general population, the estimated background risk of major birth defect and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively. **Lactation:** Risk Summary: There is no information regarding the presence of NOVOSEVEN® RT in human milk, the effect on the breastfed infant, and the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for NOVOSEVEN® RT and any potential adverse effects on the breastfed infant from NOVOSEVEN® RT or from the underlying maternal condition. **Pediatric Use:** Clinical trials enrolling pediatric patients were conducted with dosing determined according to body weight and not according to age. Hemophilia A or B with Inhibitors: During the investigational phase of product development NOVOSEVEN® was used in 16 children aged 0 to <2 years for 151 bleeding episodes, 27 children aged 2 to <6 years for 140 bleeding episodes, 43 children aged 6 to <12 for 375 bleeding episodes and 30 children aged 12 to 16 years for 446 bleeding episodes. In a double-blind, randomized comparison trial of two dose levels of NOVOSEVEN® in the treatment of joint, muscle and mucocutaneous hemorrhages in hemophilia A and B patients with and without inhibitors 20 children aged 0 to <12 and 8 children aged 12 to 16 were treated with NOVOSEVEN® in doses of 35 or 70 micrograms per kg dose. Treatment was assessed as effective (definite relief of pain/tenderness as reported by the patient and/or a measurable decrease of the size of the hemorrhage and/or arrest of bleeding within 8 hours [rated as excellent = 51%], within 8-14 hours [rated as effective = 18%] or after 14 hours [rated as partially effective = 25%]) in 94% of the patients. NOVOSEVEN® was used in two trials in surgery. In a dose comparison 22 children aged 0 to 16 years were treated with NOVOSEVEN®. Effective intraoperative hemostasis (defined as bleeding that had stopped completely or had decreased substantially [rated as effective = 86%] or bleeding that was reduced but continued [rated as partially effective = 9%]) was achieved in 21/22 (95%) patients. Effective hemostasis was achieved in 10/10 (100%) patients in the 90 mcg/kg dose group and 10/12 (83%) in the 35 mcg/kg dose group at 48 hours; effective hemostasis was achieved in 10/10 (100%) in the 90 mcg/kg dose group and 9/12 (75%) in the 35 mcg/kg dose group at 5 days. In the surgery trial comparing bolus (BI) and continuous infusion (CI) 6 children aged 10 to 15 years participated, 3 in each group. Both regimens were 100% effective (defined as bleeding has stopped completely, or decreased substantially) intra-operatively, through the first 24 hours and at day 5. At the end of the study period (Postoperative day 10 or discontinuation of therapy) hemostasis in two patients in the BI group was rated effective and hemostasis in one patient was rated as ineffective (defined as bleeding is the same or has worsened). Hemostasis in all three patients in the CI group was rated as effective. Adverse drug reactions in pediatric patients were similar to those previously reported in clinical trials with NOVOSEVEN®, including one thrombotic event in a 4 year old with internal jugular vein thrombosis after port-a-cath placement which resolved. Congenital Factor VII deficiency: In published literature, compassionate use trials and registries on use of NOVOSEVEN® in congenital Factor VII deficiency, NOVOSEVEN® was used in 24 children aged 0 to <12 years and 7 children aged 12 to 16 years for 38 bleeding episodes, 16 surgeries and 8 prophylaxis regimens. Treatment was effective in 95% of bleeding episodes (5% not rated) and 100% of surgeries. No thrombotic events were reported. A seven-month old exposed to NOVOSEVEN® and various plasma products developed antibodies against FVII and rFVIIa [*see Adverse Reactions and Overdosage*]. Glanzmann's Thrombasthenia: In the Glanzmann's Thrombasthenia Registry, NOVOSEVEN® was used in 43 children aged 0 to 12 years for 157 bleeding episodes and in 15 children aged 0 to 12 years for 19 surgical procedures. NOVOSEVEN® was also used in 8 children aged >12 to 16 years for 17 bleeding episodes and in 3 children aged >12 to 16 years for 3 surgical procedures. Efficacy of regimens including NOVOSEVEN® was evaluated by independent adjudicators as 93.6% and 100% for bleeding episodes in children aged 0 to 12 years and >12 to 16 years, respectively. Efficacy in surgical procedures was evaluated as 100% for all surgical procedures in children aged 0 to 16 years. No adverse reactions were reported in Glanzmann's thrombasthenia children. **Geriatric Use:** Clinical studies of NOVOSEVEN® RT in congenital factor deficiencies and Glanzmann's thrombasthenia did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

OVERDOSAGE: Dose limiting toxicities of NOVOSEVEN® RT have not been investigated in clinical trials. The following are examples of accidental overdose. One newborn female with congenital factor VII deficiency was administered an overdose of NOVOSEVEN® (single dose: 800 micrograms per kg body weight). Following additional administration of NOVOSEVEN® and various plasma products, antibodies against rFVIIa were detected, but no thrombotic complications were reported. One Factor VII deficient male (83 years of age, 111.1 kg) received two doses of 324 micrograms per kg body weight (10-20 times the recommended dose) and experienced a thrombotic event (occipital stroke). One hemophilia B patient (16 years of age, 68 kg) received a single dose of 352 micrograms per kg body weight and one hemophilia A patient (2 years of age, 14.6 kg) received doses ranging from 246 micrograms per kg body weight to 986 micrograms per kg body weight on five consecutive days. There were no reported complications in either case.

More detailed information is available upon request.

For information contact:
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Plainsboro, NJ 08536, USA
1-877-NOVO-777
www.NOVOSEVENRT.com

Manufactured by:
Novo Nordisk A/S
2880 Bagsvaerd, Denmark
License Number: 1261

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NovoSeven® RT
Coagulation Factor VIIa (Recombinant)

CAMP BRAVE EAGLE

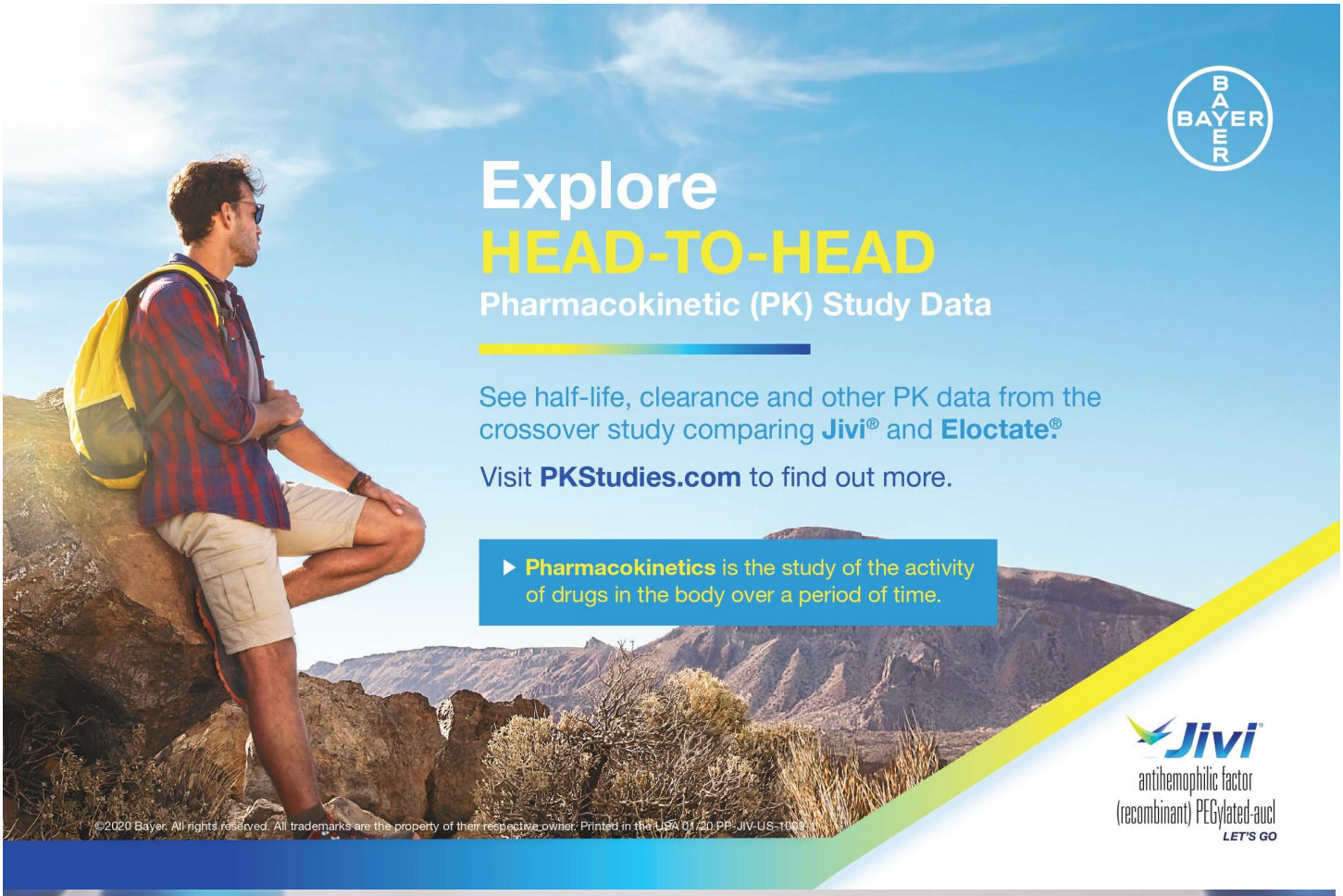
"Where the eagles soar!"

Camp Brave Eagle 2021 will be held in person this year in North Webster Indiana from June 13th to the 18th!! While we are super excited for this year there are a few changes that will be in affect for the summer of 2021 only.

- Due to decreased cabin capacity, we are unable to invite undiagnosed siblings this year
- Transportation (buses) will NOT be provided from the IHTC to camp or back this year
- Camp check-in will occur at camp only and between the hours of 1:00PM-4:00PM(EST) on June 13th
- There will be NO awards ceremony for parents to attend on the last day of camp
- There will be NO Leaders in Training program this year
- We have extended the age for campers from 16 to 17(2021 only)

There is much more to tell but the biggest thing to do now is to register before the Friday, April 23rd, 2021 deadline! You can register online at www.campbraveeagle.org.

*Please contact Angel DiRuzza if you have any questions or concerns at 317-570-0039.



Sigilon is developing functional cures for patients living with chronic diseases, including rare blood disorders

In a Phase 1/2 clinical study

Hemophilia A

In Development

FVII Deficiency

Hemophilia B

Here to Listen:
Meet the Patient Advocacy Team

SAY HELLO TO JAMES

He has hemophilia A and has gone through two major surgeries while keeping to his factor regimen with the support of his hemophilia care team

"RECOVERY WAS TOUGH, BUT I LEARNED I HAD MORE SUPPORT THAN *I THOUGHT POSSIBLE*."

HELLO FACTOR

Read stories like James' in *Hello Factor* magazine:
BleedingDisorders.com

Takeda

HEMOPHILIA OF INDIANA

Bowling for Bleeding Disorders

When: April 17th, 2021 from 10am-1pm
Where: Pinheads (13825 Britton Park Rd, Fishers, IN 46038)
What: Help raise bleeding disorder awareness and raise $$ for Hemophilia of Indiana's Judy Moore Scholarship Program

HOW TO GET INVOLVED:

#1) Register to attend the Bringing Awareness through Bowling Program online at www.hoii.org/events/bowling
(Program includes education program and pizza lunch)

#2) Form your team (up to 4) and ask friends/family/coworkers to support you and your by donating at by credit card at www.hoii.org/donate or cash/check! No amount is too little or too much!!

*All donations are tax deductible!
*All participant must be registered!
***Registration deadline Friday, April 9, 2021**
*Contact Kristy McConnell @ kmcconnell@hoii.org or (317) 570-0039 with any questions!

Presenting Sponsor:

INDIANA HEMOPHILIA & THROMBOSIS CENTER, INC.

HEMOPHILIA OF INDIANA

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(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!

- Bowling for Bleeding Disorders - April 17th
- Camp Brave Eagle - June 13th - 18th
- Sunset at Polo - July 2nd

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!!!