Vital Link

...For Hoosiers Living with a Bleeding Disorder

HEMOPHILIA OF INDIANA

July 2020

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

Designed by: Kristy McConnell

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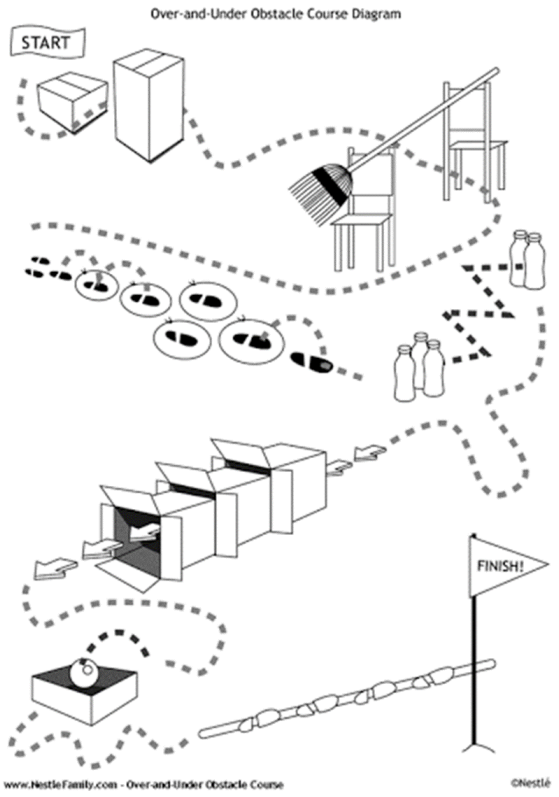
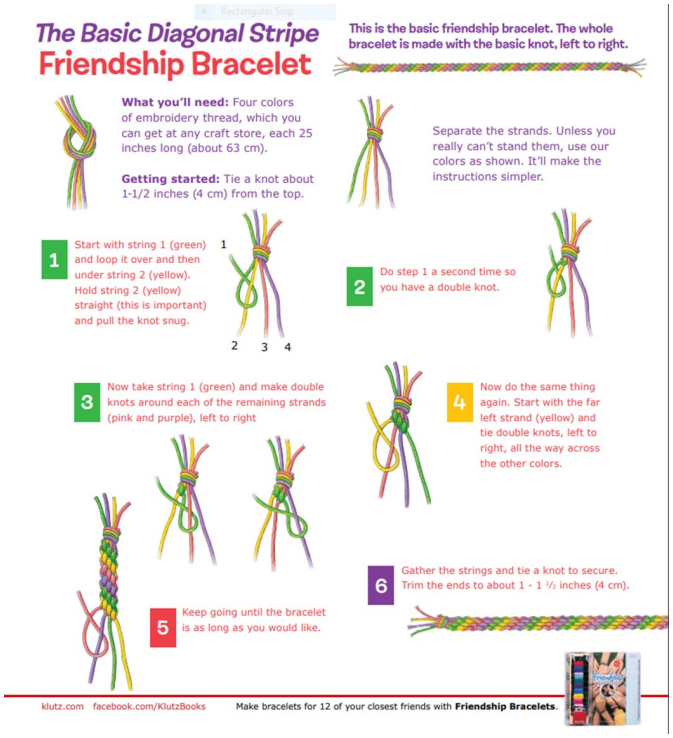
www.hoii.org

2020 Virtual Camp Brave Eagle

2020 hasn't exactly gone as planned for Hemophilia of Indiana (HoII) and the world as a whole! However, HoII continues its mission of being dedicated to empowering the bleeding disorders community through education and support, while advocating access to quality care and product safety. Due to the current COVID-19 pandemic, the 2020 Camp Brave Eagle had to be cancelled and a Virtual Camp was created in its place! Led by HoII's Community Outreach Coordinator, Angel DiRuzza, a new virtual agenda was created. Angel put together a detailed activity booklet with scheduled activities and themes for each day for campers to participate in at home. The scheduled activities and theme days were based off of what the campers would of participated in at live camp. The campers also participated in nightly web calls that allowed them to discuss the day's activities, bleeding disorder education, and best of all interact with their fellow campers! The scheduled activities included making friendship bracelets, sports, make your own obstacle course, a scavenger hunt, and making s'mores! Fun was had by all that participated and the new campers are even more excited to attend the 2021 Camp Brave Eagle! A huge thank you to all of our sponsors and donors that help make it possible to hold the 2020 Virtual Camp Brave Eagle!

Just because the 2020 Virtual Camp Brave Eagle week is over, doesn't mean the fun has to stop!! Here are some of the activity instructions to do at home all summer long!





A Huge Thank You to all of our Camp Sponsors!

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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.

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

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

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

****Community Member Corner****

Community Member Makes Over 2100 Masks during Covid-19 Crisis

By Angela DiRuzza, Community Outreach Coordinator

Hemophilia of Indiana wanted to take the opportunity to highlight one of our community members who stepped up in a big way to help others during these unprecedented times. Bobbi Craven-Risedorph, a bleeding disorders community member and longtime volunteer for Hemophilia of Indiana, used 275 yards of fabric and 650 yards of elastic to make more than 2100 masks over the last 3 months. What started out as a goal to make 40 masks for Bobbi's sister and her co-workers on a Labor and Delivery floor at a northern Indiana hospital has turned into something much, much more. The first question I asked Bobbi was if she had ever sewn before and she said she only knew how to make very basic stuff. She said she watched a lot of YouTube videos and made a few "prototypes" until she got her masks just right.

"I'm just glad that I was able to help during such an uncertain time. Obviously, they aren't a replacement for n95, but they provide a barrier and can help someone feel just that much safer".

Bobbi has sent care packages to emergency rooms, pharmacies, factories, banks, grocery stores, VA Clinics, EMS groups, nursing homes and assisted living facilities, animal rescues and even donated some to the Navajo Nation. She has sold a few of her masks to people who were not necessarily considered essential workers, but who wanted to feel more protected when they were out and about. With that money from those sales and monetary donations, she was able to purchase supplies to make more masks. Three broken sewing machines, shipments to 22 states, and binge-watching Netflix for hours later she is not done yet! Bobbie has an order to make 60 more masks in the coming week and I am sure many more in the months ahead.

On behalf of myself and Hemophilia of Indiana, we want to say a huge thank you to Bobbi! Thank you for all your doing now to help people feel safe in very uncertain times and thank you for all you do for the bleeding disorders community in Indiana!!

Do you know a member of the bleeding disorders family that has gone above and beyond for their community??? Contact Kristy McConnell or Angel DiRuzza at the Hemophilia of Indiana office with their story to be potentially featured in the next issue of the ***Vital Links*** Newsletter!

HEMOPHILIA OF INDIANA

Unite for Bleeding Disorders

SAVE THE DATE!

Participate. Volunteer. Donate.

Date: Saturday, September 12, 2020
Registration Check-In Time: 9:00am
Walk Start Time: 10:30am
****Start time subject to change due to increased park attendance****
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! Now more than ever is the time that we need to Unite as a community!

To get more information and to register go to
https://hoii.org/events/walk/ !!!

Local Walk Manager:
Kristy McConnell
317-570-0039 or **kmcconnell@hoii.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. 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**.

HEMLIBRA®
emicizumab-kxwh
injection for subcutaneous use | 150 mg/mL

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

HEMLIBRA®
emicizumab-kxwh
injection for subcutaneous use
150 mg/mL

Genentech
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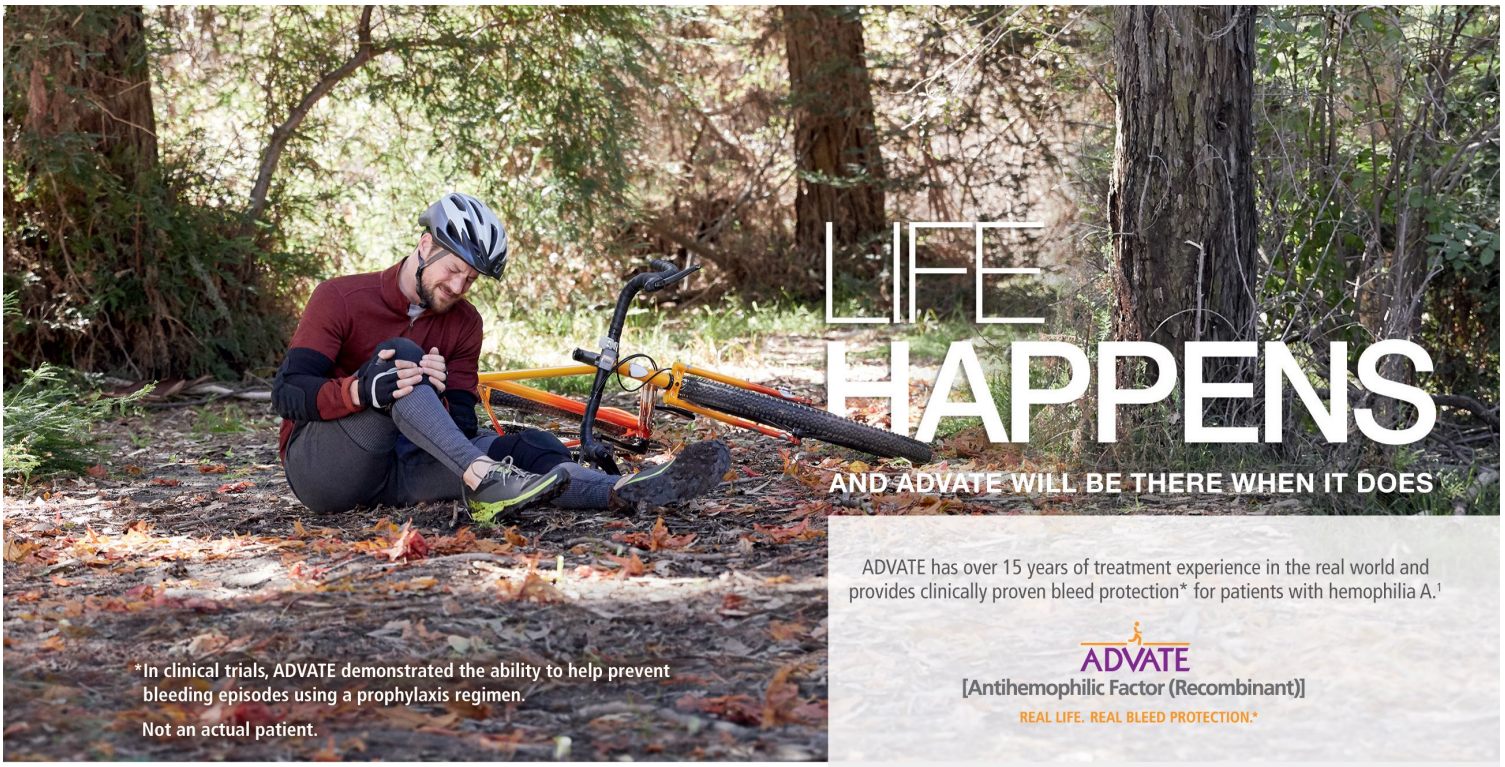

ADVATE has over 15 years of treatment experience in the real world and provides clinically proven bleed protection* for patients with hemophilia A.[1]

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.

Takeda

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.

Patented: see https://www.takeda.com/en-us/patents/

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Issued: 12/2018

US-ADV-0030v1.0 02/20

Takeda

Hemophilia of Indiana's 2020 Virtual Annual Meeting

Similar to the 2020 Camp Brave Eagle, Hemophilia of Indiana has made the difficult decision to cancel the live event 2020 Annual Meeting. The safety of our patients and families is of the upmost importance to our organization and sponsors. Holl is excited to announce that we will be hosting a Virtual Annual Meeting on Saturday, August 15th! Our team is working hard on the agenda, but will be similar to the live event with two key note sessions in the morning, a virtual "meet & greet" round robin style with our event sponsors, and 3 afternoon break out sessions. Multiple topics will be presented in the afternoon breakout sessions! Registration information will be available online at www.hoii.org/educationalprograms/annual-meeting! Once registered, attendees will receive the agenda and sign up links for the afternoon break out sessions. Even though, we can't be together in person, we are excited for the opportunity to still be able to bring an incredible day of education to our community!!

HEMOPHILIA OF INDIANA

2020 Virtual Annual Meeting

Thank you to our Sponsors!

Title Sponsors:

Indiana Hemophilia & Thrombosis Center

Genentech
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BIOMARIN

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Biotherapies for Life™

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

Pfizer

A FULLY VIRTUAL CONFERENCE

August 1-8, 2020

NHF
#NHF2020
Bleeding Disorders Conference

SYMPOSIUM IS VIRTUAL!

August 24–29, 2020

CHARTING OUR Future

When it comes to your hemophilia A treatment

Move beyond the threshold[a]

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

In adults and adolescents, factor levels stayed:

At or above **3%** for 100% of the time[a,c]

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

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

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**

novo nordisk®

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

Discover more at **esperoct.com**

22-hour

average half-life in adults[e]

Flexible on the go

The only EHL product with stability up to **104°F** for up to **3 months**

- **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.

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 from the date of manufacture until the expiration date stated on the label.

ESPEROCT® may be stored at room temperature (not to exceed 86°F/30°C), for up to 12 months within the 30-month time period. Record the date when the product was removed from the refrigerator. The total time of storage at room temperature should not exceed 12 months. Do not return the product to the refrigerator.

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 86°F (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: 02/2019

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

Manufactured by:
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Novo Allé
DK-2880 Bagsværd, Denmark

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

For information about ESPEROCT® contact:
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US19ESP00010 August 2019

novo nordisk®

Publication: PEN 5.20
Column: Richard's Review

Hemophilia and Boxing: Philip Nilon

Richard J. Atwood

Let's be clear: Boxing is a dangerous sport for everyone, but especially for someone with a bleeding disorder. Even once! The risk of a head bleed far outweighs any benefit from the exercise. Ignoring this risk, some people with hemophilia attempt to box. One was Philip James Nilon (1937–1991) from Australia.

Nilon was mentioned several times in books and journals. C. B. Kerr, MB, a hematologist at the University of Sydney, mentioned Philip twice: in *The Management of Haemophilia* (1963), a small medical text that summarized the standard of care at the time; and in a 1964 article in the *Journal of Neurology, Neurosurgery and Psychiatry*. Kerr identified Philip as Case 7 or with his initials P. N. at a time before the privacy of medical information became protected by law. Anne Kearney, Philip's younger sister, wrote *The Billycart, the Boxing Tent, the Battle: Life with Haemophilia* (2013), a memoir of her brother. For his part, Philip used dismissal, denial, and deception while trying to lead a life of adventure.

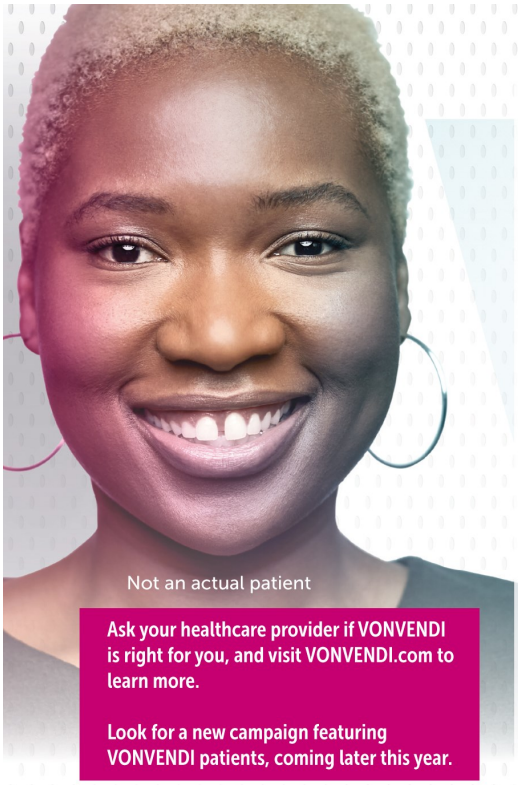
Philip was born in Ungarie, New South Wales, and grew up in Sydney. He was the sixth of seven children. He had a maternal uncle and a maternal cousin with hemophilia. Philip received the diagnosis of moderate factor VIII hemophilia. As a child, he injured his left leg, causing permanent nerve damage and a lifelong limp. Just like other boys in Sydney, Philip built a "billycart," basically a fruit box on wheels with imprecise steering for rolling down hills as fast as possible. He was knocked unconscious when he tried to scoot his billycart under a moving semi-trailer. This accident, along with others, meant that Philip spent long periods confined to bed. There he developed his natural drawing skills that, as an employed adult, he applied to technical drawings.

Philip's sister described his treatment as receiving "bottles of blood" and occasionally requiring opening a vein for access. His hematologist documented therapy using plasma for factor replacement. Philip suffered countless cerebral hemorrhages, including a notable intracerebral bleed with recovery when only age 9, in 1947. Joint bleeds, especially in ankles and elbows, limited his movement. He had a throat bleed at age 15.

When he was age 16 and six feet tall, Philip entered the Jimmy Sharman boxing booth at the Royal Easter Show. He sparred with an unbeatable professional boxer for ten bouts. Philip was knocked out cold without experiencing a brain hemorrhage, as confirmed by Prince Alfred Hospital records and by his hematologist. Surprisingly, there were no ill effects. Later, at age 23 in 1961, Philip had an accident, possibly while surfing. Doctors couldn't determine if he had a blow to the head, a spontaneous head bleed, or meningitis. Philip became delirious, then unconscious for a week due to suspected intracerebral and subarachnoid bleeds. When he recovered after plasma therapy, Philip had lingering aphasia with no memory of the event; he refused speech therapy.

Philip worked at Bennett & Wood, a transportation conglomerate in Zetland, where he applied his skills in the spare parts division. In 1983, he was the first patient with hemophilia to undergo a right knee fusion that resulted in no further bleeds. Then, in 1984, Philip was diagnosed with medically acquired AIDS after being treated for pneumocystic pneumonia. He continued to have cerebral hemorrhages. A right hip hematoma the size of a football was successfully treated with a dose of radiation. Philip rejuvenated his Catholic faith in 1990. Regrettably, his self-diagnosis of melanoma was medically confirmed, and the cancer spread to his spine, causing his death.

Philip Nilon was extremely lucky to survive numerous medically documented head bleeds. His hematologist provided the needed medical care. And his sister provided palliative care in her home at the end of his life. Because of its emotional content, Anne Kearney needed several attempts over 21 years to finish the memoir of her brother. Philip led an adventurous life, one that included an ill-advised boxing escapade.



Not an actual patient

Ask your healthcare provider if VONVENDI is right for you, and visit VONVENDI.com to learn more.

Look for a new campaign featuring VONVENDI patients, coming later this year.

Is VONVENDI® [von Willebrand factor (Recombinant)] right for your von Willebrand disease?

As an adult with von Willebrand disease (VWD), unexpected bleeds are part of my life. I talked to my healthcare provider about finding a medication I could use to help treat and control the unexpected bleeds caused by my VWD. Together, we decided VONVENDI was the right treatment to manage my bleeding episodes.

VONVENDI

+ Is used in adults (age 18 and older) diagnosed with VWD to **treat and control bleeding episodes** and **prevent excessive bleeding during and after surgery**
+ **Is the first and only recombinant von Willebrand factor (VWF),** meaning it is manufactured without human plasma or blood
+ **May be used with or without a recombinant factor VIII (rFVIII),** as instructed by your healthcare provider

VONVENDI Important Risk Information

Who should not use VONVENDI?
You should not use VONVENDI if you:
+ Are allergic to any ingredients in VONVENDI.
+ Are allergic to mice or hamsters.

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

Please see additional Important Risk Information below.

Important Risk Information (continued)

How should I use VONVENDI?
Your first dose of VONVENDI for each bleeding episode may be administered with a recombinant factor VIII as instructed by your healthcare provider.

Your healthcare provider will instruct you whether additional doses of VONVENDI with or without recombinant factor VIII are needed.

What should I tell my healthcare provider before I use VONVENDI?
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 VONVENDI passes into your milk and if it can harm your baby.
- Are pregnant or planning to become pregnant. It is not known if VONVENDI can harm your unborn baby.
- Have been told that you have inhibitors to von Willebrand factor (because VONVENDI may not work for you).
- Have been told that you have inhibitors to blood coagulation factor VIII.

What else should I know about VONVENDI and von Willebrand disease?
Your body can form inhibitors to von Willebrand factor or factor VIII. An inhibitor is part of the body's normal defense system. If you form inhibitors, it may stop VONVENDI or factor VIII from working properly. Consult with your healthcare provider to make sure you are carefully monitored with blood tests for the development of inhibitors to von Willebrand factor or factor VIII.

What are the possible side effects of VONVENDI?
You can have an allergic reaction to VONVENDI.

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 VONVENDI include: nausea, vomiting, tingling or burning at infusion site, chest discomfort, dizziness, hot flashes, itching, high blood pressure, muscle twitching, unusual taste, blood clots and increased heart rate.

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

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 VONVENDI Consumer Brief Summary on the following page and talk to your healthcare provider.

Takeda

vonvendi
[von Willebrand factor (Recombinant)]

Important facts about VONVENDI®:

This leaflet summarizes important information about VONVENDI. Please read it carefully before using this medicine. This information does not take the place of talking with your healthcare provider.

vonvendi
[von Willebrand factor (Recombinant)]

What is VONVENDI?

VONVENDI is a recombinant medicine used to replace low levels or not properly working von Willebrand factor in people with von Willebrand disease. Von Willebrand disease is an inherited bleeding disorder in which blood does not clot normally.

VONVENDI is used in adults (age 18 years and older) diagnosed with von Willebrand disease to:

- Treat and control bleeding episodes
- Prevent excessive bleeding during and after surgery

Who should not use VONVENDI?

You should not use VONVENDI if you:

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

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

What should I tell my healthcare provider before I use VONVENDI?

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 VONVENDI passes into your milk and if it can harm your baby.
- Are pregnant or planning to become pregnant. It is not known if VONVENDI can harm your unborn baby.
- Have been told that you have inhibitors to von Willebrand factor (because VONVENDI may not work for you).
- Have been told that you have inhibitors to blood coagulation factor VIII.

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

VONVENDI can cause blood clots particularly in patients with known risk factors for blood clots. Discuss this risk with your healthcare provider.

You can have allergic reactions to VONVENDI. Symptoms may include generalized itching; rash or hives; rapid swelling of the skin or mucous membranes; chest pain or tightness; tightness of the throat; low blood pressure; shock; drowsiness; nausea; vomiting; tingling, prickling, burning, or numbness of the skin; restlessness; wheezing and/or difficulty breathing; lightheadedness; dizziness; or fainting. If symptoms occur, stop using VONVENDI immediately and get emergency treatment right away.

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

What are the possible side effects of VONVENDI?

Side effects that have been reported with VONVENDI include: nausea, vomiting, tingling or burning at infusion site, chest discomfort, dizziness, hot flashes, itching, high blood pressure, muscle twitching, unusual taste, blood clots and increased heart rate. These are not all the possible side effects with VONVENDI. You can ask your healthcare provider for information that is written for healthcare professionals.

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

What else should I know about VONVENDI and von Willebrand Disease?

Consult with your healthcare provider to make sure you are carefully monitored with blood tests to measure levels of von Willebrand factor and factor VIII so they are right for you.

You may infuse VONVENDI at a hemophilia treatment center (HTC), at your healthcare provider's office or in your home. You should be trained on how to do infusions by your healthcare provider or HTC. Many people with von Willebrand disease learn to infuse VONVENDI by themselves or with the help of a family member.

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

Medicines are sometimes prescribed for purposes other than those listed here. Do not use VONVENDI for a condition for which it is not prescribed. Do not share VONVENDI 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 healthcare provider or pharmacist about Vonvendi. The FDA approved product labeling can be found at https:\\www.shirecontent.com/ PI/PDFs/ VONVENDI_USA_ENG.pdf or call 1-800-828-2088.

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.

Issued 02/2019

S48947 06/19

Takeda

Steps for Living
Education for all Life Stages

Self-Infusion: Word Game #3 (Older Kids)

Here are some common items used when you self-infuse. Can you find them?

BUTTERFLY
FACTOR
GLOVES
NEEDLE
SWAB
SYRINGE

T B G R D E R Y R
L U T O Y G T R Y
Y T N R Y T E V R
T T F L E S W R C
N E A R L B F O E
D R C L D A R E W
O F T G E W E A O
G L O V E S W S L
S Y R I N G E T Y

Self-Infusion: Word Game #4 (Older Kids)

Here are some common items used when you self-infuse. Can you find them?

BANDAGE
GAUZE
JOURNAL
TAPE
TOURNIQUET

T E U Q I N R U O T
G G A O G D O A B A
L A N R U O J E U R
T D U Q A N A E U Q
A N J Z T U T E A J
T A P E E L Q A Z E
U B O T N O U T U E
U E B R T N G T E A
E I O A R O P U G A
L D O Q B N U E R L

Hemdifferently

Exploring the science behind gene therapy research

Gene therapy research has the potential to bring an entirely new option to people with specific genetic conditions. Many gene therapies are in clinical trials to evaluate the possible risks and benefits for a range of conditions, including hemophilia. HemDifferently is here with gene therapy education, providing accurate information in a way you can understand.

Let's explore gene therapy together at **HemDifferently.com**

No gene therapies for hemophilia have been approved for use or determined to be safe or effective.

BIOMARIN®

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!

Here are some of our upcoming events…

- HoII Virtual Annual Meeting - August 15, 2020
- Course to a Cure Golf Outing - August 24, 2020
- Unite for Bleeding Disorders Walk - September 12, 2020

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!!!