Vital Link

...For Hoosiers Living with a Bleeding Disorder

HEMOPHILIA OF INDIANA

June 2022

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

Designed by: Kristy McConnell

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www.hoii.org

CAMP BRAVE EAGLE
"Where the eagles soar!"

Camp Brave Eagle began in 1999 to offer a traditional summer camp experience to children with bleeding disorders. It is a collaboration of Hemophilia of Indiana, Inc. (HoII), IHTC and YMCA Camp Crosley and encourages self-sufficiency, builds confidence, increases campers' self-esteem, and promotes a positive outlook. It also aims to strengthen the sense of community among young Hoosiers with bleeding disorders and their families. Activities include canoeing, archery, arts & crafts, swimming, and so much more! This year's camp took place June 12-17 with 123 excited campers! In addition to the "typical camp" activities, each camper participated in self-infusion training. 99 campers earned their "Big Stick" by successfully completing the self-infusion training! This training is an essential part of camp to help teach campers independence and increase their self confidence. For siblings, this training allows them to gain empathy for their affected sibling and help them to become an even bigger supporter. It was a hot week at camp, but thanks to the dedicated staff, there was a constant supply of water and gatorade! Thank you to all of our donors and Camp Brave Eagle sponsors that help make Camp Brave Eagle possible!! Check out our Facebook page (HemoIndy) for more pictures from this fun week!

Thank you!

CAMP BRAVE EAGLE
"Where the eagles soar!"

2022 Camp Sponsors!!

Thank you!

Takeda

Indiana Hemophilia & Thrombosis Center

Genentech
A Member of the Roche Group

Pfizer

novo nordisk®

CASCADE
HEMOPHILIA CONSORTIUM
SINCE 1994

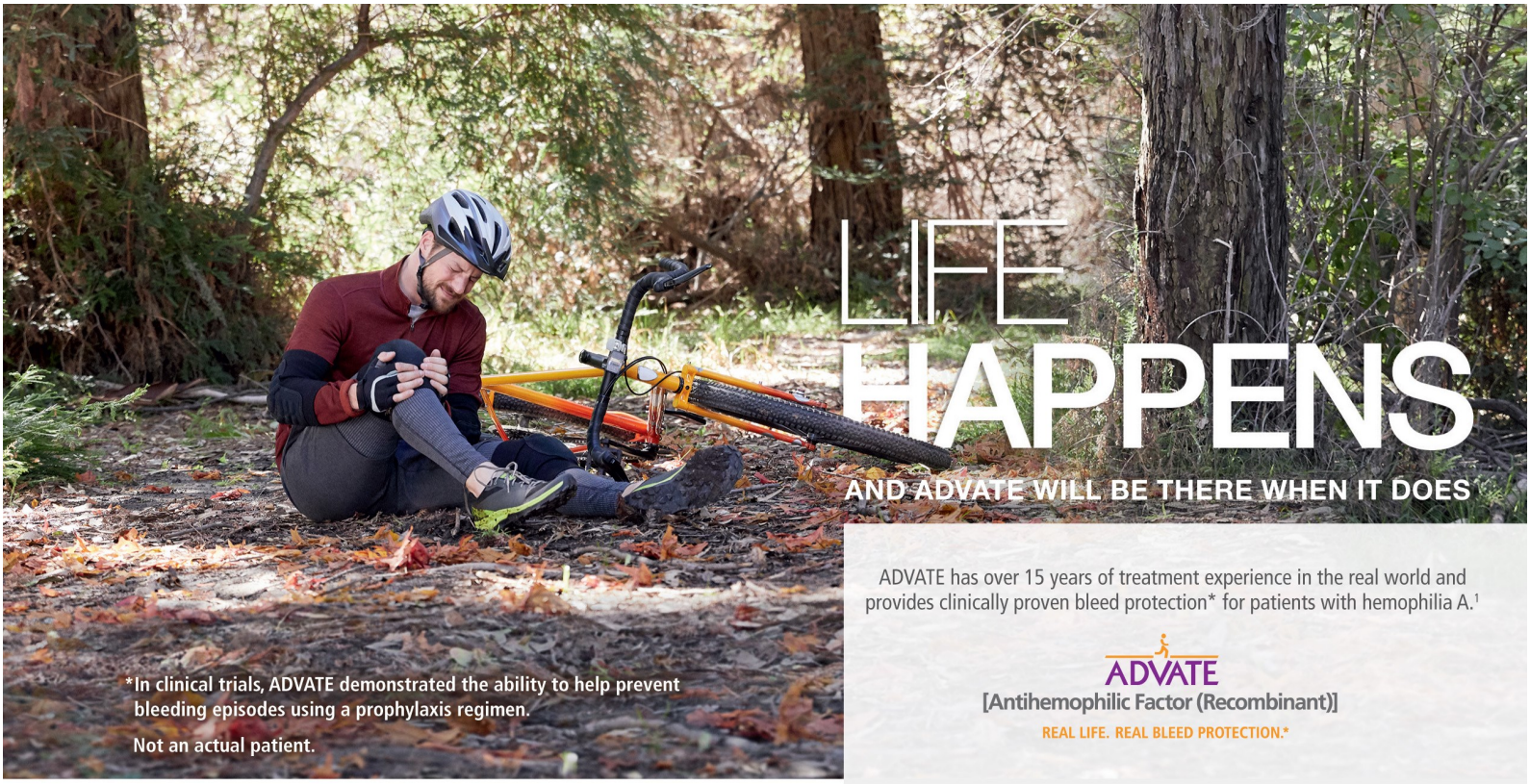
CVS specialty®

sanofi

The IHTC is home to Indiana's experts in rare bleeding & blood disorders, including:
Hemophilia | HHT | HVLM | Thrombosis & Clotting | Sickle Cell Disease | von Willebrand Disease

The Indiana Hemophilia & Thrombosis Center (IHTC) provides advanced care for both adult and pediatric patients with rare bleeding and blood disorders. As Indiana's only federally recognized hemophilia treatment center, IHTC is one of the nation's largest HTCs, delivering innovative, multi-disciplinary care in Indianapolis and at outreach clinics across the state. Visit ihtc.org

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



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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US-ADV-0030v1.0 02/20

Takeda

2022 Course to a Cure

The 2022 Course to a Cure was held on Monday, June 6th at the beautiful Maple Creek Country Club. 29 teams participated in this year's event. This was the 37th year for this event making it Hemophilia of Indiana's oldest fundraiser. The event included a very successful silent and live auction. All proceeds from the Course to a Cure directly benefit the programs and services Hemophilia of Indiana provides to the bleeding disorders community of Indiana. HoII would like to thank all of our donors and sponsors that made this year's event a huge success!! More pictures posted on our Website (www.hoii.org/events/golf)!











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

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

OnceWeeklyForHemophiliaB.com

Pfizer

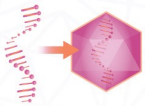
DO YOU WONDER HOW GENE TRANSFER THERAPY IS DESIGNED TO WORK?

Gene transfer is one method of gene therapy being researched that aims to introduce a working gene into the body to produce a needed protein that is missing or dysfunctional.

THE 5 STEPS OF GENE THERAPY RESEARCH

STEP 1

Create a working gene in a lab



STEP 2

Build a therapeutic vector to protect and transport the working gene into the body

STEP 3

Determine eligibility for gene therapy based on a number of factors

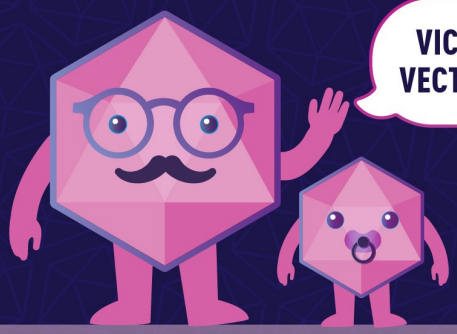
STEP 4

Deliver a larger number of the working gene via a one-time infusion

STEP 5

Researchers monitor the safety and efficacy through frequent visits and blood tests

Researchers are studying how gene therapy may be able to help patients with monogenic (single-gene mutation) conditions, like **Huntington's disease**, **hemophilia**, or **cystic fibrosis**. BioMarin is here to help turn this complex science into clarity.



DID YOU KNOW?

Gene transfer therapy is not designed to replace or edit the existing gene, which means that the mutated gene could still be passed on to future generations.

GENE THERAPY BIOMARIN LEARNING ACADEMY

Curious about ***how*** a therapeutic vector is built and what the eligibility requirements for gene therapy research may be? Sign up for the *BioMarin Gene Therapy Learning Academy* to get more details about gene therapy research delivered straight to your inbox.

SCAN CODE

HemDifferently.com

Follow us on Facebook for more interesting facts about investigational gene therapy.
@GeneTherapyResearch

Hemdifferently
Presented by BIOMARIN

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

Unite for Bleeding Disorders

HEMOPHILIA OF INDIANA

Hemophilia of Indiana

Saturday, August 20, 2022
Walk Starts 10:30am
(Check-in Time 9:00 am)

Fort Harrison State Park
(Delaware Shelter Area)
Indianapolis, IN

Contact Kristy McConnell at 317.570.0039
or email her at **kmcconnell@hoii.org**

HEMOPHILIA ALLIANCE www.uniteforbleedingdisorders.org Takeda

Every summer has a story, stay safe creating yours

The IHTC team offers these physical, emotional health tips

Leaves of 3: Let them be

There are several plants that can cause irritation when touched. The best way to identify poisonous plants while exploring the great outdoors is to become familiar with pictures of varieties growing in your area. The "Rule of Three" helps and is simple to remember. *"Leaves of three: Let it be!"* Learn more: www.wnit.org

The 'Don't Touch Me Plants' - WNIT. https://www.wnit.org/outdoorelements/pdf/donttouchmeplants.pdf.

Pointed leaves
Grouped in threes

Rounded leaves
Grouped in threes

Stems contain up to 13 leaflets
Often found by water

Summer Health Tips

1. **Cover up and wear sunscreen.** Protect your skin from ultraviolet rays which can cause skin cancer. Choose a sunscreen with at least SPF15. Stay safe around water, too.
2. **Wear a bike helmet.** Bike helmets save lives. Follow rules of the road and obey traffic laws and signs. Also consider elbow and knee protection.
3. **Wear insect repellant to prevent bites.** Check for ticks when coming in from outside.
4. **Be mindful of fireworks.** Follow all precautions, as these are dangerous. There is no harm in letting the professionals do the work for you while at a community event.
5. **Keep hydrated.** Have plenty of water available all summer when in the heat. Kids playing and people working outside should carry a cooler of water. Take plenty of breaks.

"CDC's Eight Tips for Safe and Healthy Summertime Work and Play." May 2019, https://www.cdc.gov/media/

Mental Health Awareness

The COVID-19 pandemic has contributed to rising rates of mental health challenges such as depression and anxiety, substance misuse, and serious thoughts of suicide. Some people are unsure how to recognize mental health problems, unaware that effective treatment is available and easy to access.

Due to poor understanding and stigma, many people suffer needlessly in silence while their conditions go untreated. If you or a loved one haven't been feeling like yourself lately, you may have a mental health issue that needs treatment. If you need assistance finding mental health treatment, please call the IHTC Mental Health Team for assistance at 317-871-0000.

What is mental health awareness?

- Increasing the understanding that mental health is an essential part of overall health and wellbeing
- Improving the recognition of mental health symptoms by both individuals and healthcare systems to improve access to mental health services
- Providing information about treatments available to encourage individuals to seek help
- Decreasing the stigma around mental health problems and treatment

Mental health includes our emotional, psychological, and social wellbeing. It affects how we think, feel, and act. It also helps determine how we handle stress, relate to others, and make choices. Mental health is important at every stage of life, from childhood and adolescence through adulthood.

Common signs of a potential mental health problem

Recognizing a potential mental health problem is the first step to feeling better:

- *Long-lasting periods of sadness or irritability*
- *Excessive fear, worry or anxiety*
- *Social withdrawal*
- *Changes in sleep (too much, too little)*
- *Changes in appetite (increase or decrease)*
- *Impulsive decision making*
- *Turning to drugs or alcohol in moments of distress*
- *Suicidal thoughts*

18%

of adolescents (ages 12-17) report the pandemic had a significant negative impact on their mental health

Indiana Hemophilia & Thrombosis Center

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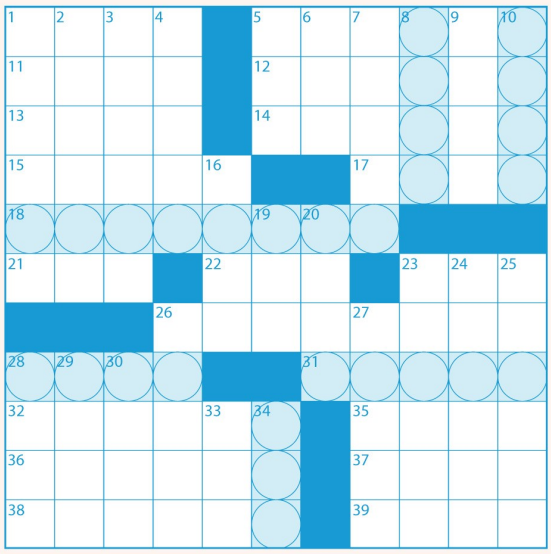
CAN YOU SOLVE FOR A DIFFERENT HEMOPHILIA A TREATMENT?

Test your HEMLIBRA knowledge



ACROSS

1. Wine barrel
5. Deep fissures
11. Mideast gulf port
12. District
13. Ripped
14. Familiar with
15. Mean
17. Roost
18. The #1 prescribed prophylaxis for people with hemophilia A without factor VIII inhibitors*

*According to IQVIA claims data from various insurance plan types from April 2020 - May 2021 and accounts for usage in prophylaxis settings in the US.

21. Calendar divs.
22. Regret
23. Banquet hosts (abbr.)
26. International travel necessity
28. Check out the _____ treated bleeds data with HEMLIBRA
31. Number of dosing options HEMLIBRA offers

† Number of people with hemophilia A treated as of October 2021.

32. Small hole in lace cloth
35. Central Plains tribe
36. Melodic
37. Towering
38. Reduce
39. Spanish cheers

DOWN

1. Memorable, as an earworm
2. Devotee
3. Medical fluids
4. Prepare to propose, perhaps
5. PC's "brain"
6. Owns
7. Concert venue
8. See Medication Guide or talk to your doctor about potential _____ effects
9. Winter hrs. in Denver and El Paso
10. HEMLIBRA is the only prophylactic treatment offered this way under the skin
16. Pre-Euro currency in Italy
19. Subway alternative
20. Relax
23. Human
24. New Orleans cuisine
25. Mentally prepares
26. Collared shirts
27. Instagram post
28. Ardent enthusiasm
29. Brontë heroine Jane
30. Old Portuguese coins
33. Opposite of WNW
34. More than_____ thousand patients have been treated with HEMLIBRA worldwide†

SOLUTIONS

Across: 1. cask, 5. chasms, 11. Aden, 12. parish, 13. tore, 14. used to, 15. cruel, 17. nest, 18. HEMLIBRA, 21. yrs, 22. rue, 23. MCs, 26. passport, 28. zero, 31. three, 32. eyelet, 35. Otoe, 36. anose, 37. tall, 38. lessen, 39. oles

Down: 1. catchy, 2. adorer, 3. serums, 4. kneel, 5. CPU, 6. has, 7. arena, 8. side, 9. MSTs, 10. shot, 16. lira, 19. bus, 20. rest, 23. mortal, 24. Creole, 25. steels, 26. polos, 27. photo, 28. zeal, 29. Eyre, 30. Reis, 33. ESE, 34. ten

Discover more at HEMLIBRA.com/answers

INDICATION & IMPORTANT SAFETY INFORMATION

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
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.

Your body may make antibodies against HEMLIBRA, which may stop HEMLIBRA from working properly. Contact your healthcare provider immediately if you notice that HEMLIBRA has stopped working for you (eg, increase in bleeds).

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: 12/2021

Genentech
A Member of the Roche Group

Judy Doyle

Patient advocate

About Judy

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

Hemophilia Community Liaison

OH, IN

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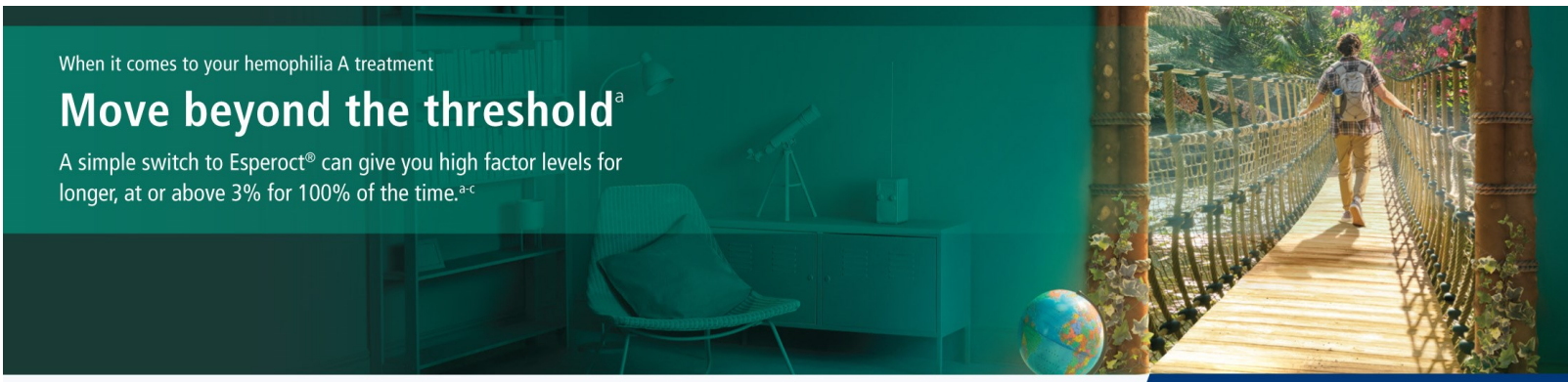

[a]Trough level goal is 1% for prophylaxis.
[b]Compared with standard half-life products.
[c]Data shown are from a study where 175 previously treated adolescents and adults received routine prophylaxis with Esperoct® 50 IU/kg every 4 days. Pre-dose factor activity (trough) levels were evaluated at follow-up visits. Mean trough levels for adolescents (12-<18 years) were 2.7 IU/dL.

Discover more at **Esperoct.com.**

What is Esperoct®?

Esperoct® [antihemophilic factor (recombinant), glycopegylated-exei] is an injectable medicine to treat and prevent or reduce the number of bleeding episodes in people with hemophilia A. Your healthcare provider may give you Esperoct® when you have surgery

- Esperoct® is not used to treat von Willebrand Disease

IMPORTANT SAFETY INFORMATION

Who should not use Esperoct®?

- You should not use Esperoct® if you are allergic to factor VIII or any of the other ingredients of Esperoct® or if you are allergic to hamster proteins

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

- Do not attempt to do an infusion yourself unless you have been taught how by your healthcare provider or hemophilia treatment center
- Call your healthcare provider right away or get emergency treatment right away if you get any signs of an allergic reaction, such as: hives, chest tightness, wheezing, dizziness, difficulty breathing, and/or swelling of the face

What should I tell my healthcare provider before using Esperoct®?

- Before taking Esperoct®, you should tell your healthcare provider if you have or have had any medical conditions, take any medicines (including non-prescription medicines and dietary supplements), are nursing, pregnant or planning to become pregnant, or have been told that you have inhibitors to factor VIII
- Your body can make antibodies called "inhibitors" against Esperoct®, which may stop Esperoct® from working properly. Call your healthcare provider right away if your bleeding does not stop after taking Esperoct®

What are the possible side effects of Esperoct®?

- Common side effects of Esperoct® include rash or itching, and swelling, pain, rash or redness at the location of infusion

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

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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:
Novo Nordisk A/S
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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Plainsboro, NJ 08536, USA
1-800-727-6500

US19ESP00010 August 2019

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*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!

- Annual Meeting - August 13th & 14th
- Unite for Bleeding Disorders Walk - August 20th
- Polo At Sunset - September 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!!!