HBDA Quarterly Newsletter

Summer Edition 2022 | Rick Dinkins, Chairman
Volume 54 | Vicki Jackson, Executive Director

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HBDA
Hemophilia and Bleeding Disorders of Alabama, Inc.

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Rick Dinkins - Chairman
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Words from the Board

I hope everyone is having a great summer and looking forward to the changing colors that the cooler fall temperatures will bring. A new school year is just around the corner, and we were proud to offer our "School Supply Assistance" program once again through the Clot Line. With the strained economy affecting all of us, many of our families were able to benefit from this program for the upcoming school year.

Our summer camp was a "Marvel-ous" event!! Camp Clot Not, provided a wonderful camping experience for all our repeat campers, plus an exciting experience for 6 brand new campers this year. You will read about their first-time camp experience in the following pages with our "Camp Testimonials" section. You can just feel the joy they experienced as they write about the newfound friendships, and the fun-filled days that Camp Clot Not offered. Although the temperatures averaged over 100+ degrees each day, there were many opportunities to cool of with plenty of pool time, a 22-foot water slide, canoeing and much more. The kids also enjoyed archery, a Marvel themed scavenger hunt and several "minute to win it" Infinity War Challenges to promote teambuilding and excitement. A great time was had by all the kids as well as the staff.

We were blessed to have many of our industry partners that volunteered their time and talents as counselors, lifeguards, and other staff positions, to help make this one of the best camps ever! We are thankful that many of our older kids come back each year to train as future camp leaders in our "LIT Program", and even volunteer as counselors when they become adults. A special thank you to everyone who helped make Camp Clot Not a very special time for the kids!

We have several exciting events to come in 2022, offering each of you the opportunity to fellowship with your peers as well as learn new information pertinent to the hemophilia community. Camp Harvest, our Family Educational Weekend, is scheduled for October 21-23 at Children's Harbor in Alexander City. As always, Camp Harvest promises to offer many opportunities to learn about new treatments and therapies, as well as a great opportunity to enjoy activities with other families in a beautiful fall setting at Lake Martin.

On November 11th we have our annual "Tee It Up for Hemophilia" golf tournament fundraiser, which I personally am excited about, as well as our Year End Luncheon on December 10th. Our golf tournament will be held at the beautiful Robert Trent Jones Golf Trail in Prattville Alabama, and this year, Children's Harbor has offered us the Lodge with a beautiful view of the lake, as our venue for the End of the Year Luncheon.

We hope to see each of you at one or all the above-mentioned events, and hope you will spread the news about HBDA, Inc. to other families that you know who are affected by bleeding disorders so that they too can benefit from the many programs and opportunities we offer our members!

Thanks for your time and Happy Fall,

Van Rushton
Board Treasurer

Truly I tell you, whatever you did for one of the least of these brothers and sisters of mine, you did for me.

NIV
Matthew 25:40

HBDA Camp Clot Not 2022

“Faith is my sword. Truth is my shield. Knowledge is my armor.” - Dr. Stephen Strange

The Marvel Multiverse was Camp Clot-Nots theme for 2022. Our program empowered the campers to have faith in ones’ self while being challenged. Campers expanded their personal knowledge about their bleeding disorder and learned the strength behind being part of a team. The journey had many challenges, risks and rewards, but the fundamental element that unified everyone was pure joy. Each camper learned about their inner hero and the rewards of working as a team.

Camp Clot-Not was divided by cabin groups but together formed the Avengers and the Agents of Shield. The “Avengersons” were 6-8 years old, The “Realm Rovers” were 9-12 years old, the “X-Ternals” were 13-15 years old, the “Galaxy Gals” were 10-15 years old girls, “The Guardians” were the LIT’s and each group had an LIT working with an “Avenger” Counselor. The “Multiverse Nurses” were the camp Nurses; Juli Mason and Linda Stepien, who managed all of the medical education, treatments, multiverse health concerns and covid testing. When everyone was united together we comprised the Multiverse of Camp Clot-Not.

At the top secret SHIELD Headquarters in Atlanta new SHIELD Agents were enlisted to answer the call for help by the Avengers to find and protect the infinity stones. Thanos, Michael McElhaney, appeared to discredit the Avengers and tried to divide the SHIELD Agents when Ironman / Tony Stark, Tyler Blair, gave the data briefing while closely working alongside all of the Avengers. The mission was laid out and the Infinity Stone scavenger hunt began.

While at camp the agents garnered new skills, such as archery and swimming to become stronger when in the field and thanks to the “Minute to Win it Infinity War Games” the agents learned speed, precision and teamwork.

During the “Shark Tank Super Hero Game” the Avengersons, Realm Rovers, X-Ternals and Galaxy Gals worked creatively with their Guardian to develop the best superhero in order to win the prize from the Avengers.

Days before camp was to start, the Black Widow (Sophie Johnson) and the Guardian of the Galaxy Gals (Alexandra Hall) agreed to save the arts and crafts program from elimination when the director became sick. Both Sophie and Alex brought their unique talents to the program and showed each camper how to create their own paracord bracelets.

Camp Clot-Not cannot begin to name all of the counselors and LIT’s right now, but what I can say is the Avengers, the Guardians and the Multiverse Nurses make up one of the most impressive group of superhero’s any bleeding disorder community has ever known. During camp many challenges and public health concerns disrupted camp but these challenges appeared to strengthen the camp and let the fun of camp prevail, and everyone worked closely as an impressive Multiverse team.

In closing I would like to express my gratitude to every camper, volunteer, nurse and staff member that made Camp Clot-Not’s Marvel Multiverse a camp to remember. In the words of Tony Stark - “It’s not enough to be against something. You have to be for something better.”

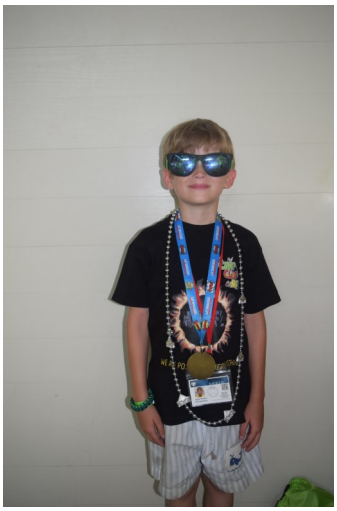
Lee Hall - Activities Director

HBDA Camp Clot Not 2022

HBDA Camp Clot Not 2022 - Camper Awards











Counselor's Choice Awards By Group

Luke B - Avengersons

Bentley G - Realm Rovers

Alex L - X-Ternals

Makenzie C - Galaxy Gals

Big Stick Awards

Christian G

Madilynn C

Tucker V

Brody B

Sophie J

Camper Awards

Luke B - Best First Time Camper

Ty P - "I'll Do It" Camper

Robert M - Clean Camper Award

Bentley G - Best Mentoring Camper

Abi D - Best Overall Camper

William S - Most-Spirited Camper

HBDA Camp Clot Not 2022 - First Time Camper Testimonials

NyAnnah: It was great and I really enjoyed it. I really enjoyed the campers and the staff. It was also super fun to be around people my age that have a bleeding disorder similar to what I do, thats something I hadn't had before. It was also nice knowing that they're other people struggling too and its not just me. I appreciate that they let me be a teenager and let me explore and ask questions to learn. I loved it and would definitely go again!!!

VaShette: We (her dad and I) truly appreciate the opportunity to have her attend and learn that she is not alone on this journey (we have felt that quite often until we became part of the HBDA family). She was reluctant to go (being the newbie), but came back all smiles with new friends similar to her. We couldn't ask for a better outcome! Thank you HBDA for making us a part of the family!!!

Sarah: This year was my son's first year to attend Camp Clot Not. Last year, we signed Robert up to go, but the last minute, he backed out because his little brother was being born, and we were moving. This year we started talking about going to camp early. He thought sleeping in the woods would be cool! Initially, he was excited, but as the day got closer, he became more anxious. He was upset that his family could not come with him. We told him that he would have a great time, packed his bag up, and drove to camp.

He asked a lot of questions as we were pulling in- where would he be sleeping and what if someone was mean to him. I told him that everyone would be really nice, but that he should tell an adult if anyone was mean to him. As we stood in line to turn in his medicine, one of the counselors started talking to him. They talked about Marvel Heroes and the fact that they were both on Hemlibra. Robert started showing off his spider man moves! By the time we went back to talk to the nurses, he was ready to go. He gave me a quick kiss on the cheek and ran off! When I realized he was gone, I was the one who ended up crying. My baby boy was over his initial fears and ready to go have fun with his new friends. I probably texted Amanda and Vicki daily asking for all sorts of updates, but he had a great time. After camp, he said he loved the water slide and pool. He had a great time at Camp and cannot wait to go back next year. Maybe next year he will even get "The Big Stick" award!

Luke: I liked the pool and the scavenger hunts. My most favorite part was wrestling on the mat in the lake. I loved all my counselors and I made new friends.

Tera: From a parent's standpoint I was nervous to send him but Amanda answered all of my questions and made me feel at ease. From the time we walked in the doors the counselors were amazing and made everyone feel comfortable. I had no doubt that he was in good hands. He is still talking about camp and is still carrying around his awards.

Tucker - My first time at camp was awesome. I was nervous but it was so much fun. My favorite thing was that all the kids had hemophilia. I did my own factor and got my big stick award. I can't wait to go back.

Britnee - Since we went to our first event with HBDA when tucker was 6 months old, we could not wait until he was old enough to attend their summer camp. Although it was tough letting my baby leave for a week, we are so blessed he was able to attend Camp Clot Not. HBDA does a fantastic job with their camp, and I know how much they love and care for every child that walks through their doors. Tucker is still talking about all the fun things he got to do, and all the people he met. He was so proud of himself getting his big stick award and said he wants to go back to Camp Clot Not every summer!

HBDA Camp Clot Not 2022 - First Time Camper Testimonials

Clay: This was my first year at Camp Clot Not. There were many fun activities at camp it was hard to not like them all. The food at camp was delicious. My favorite meal was probably their mac & cheese and hotdogs. The cabins were very nice air-conditioned and had great bathrooms. The water was always hot. My cabin had a great view of the lake. The decorations for the marvel theme were phenomenal and they put on a good show in the end, and it was fun going out late night and looking for the infinity stones.

My top five favorite things about camp were hard to choose my number five was probably the big, huge waterslide. My fourth was probably going out late night and collecting infinity stones to make sure that Thanos did not rule the galaxy. Number three my third favorite was probably the pool it had a huge waterslide and I always got to play two hand touch football with my friends. My second favorite was probably archery I had five shots and on the very last shot I got to pop the balloon it was fun. My number one favorite was probably getting to play basketball every single day it was really fun, and we got to play some really fun games like horse, pig, knockout and category. At the end of camp, I left having lots of friends some of them I even talk to today because of video games I had the best experience of camp I could ever have. I had lots of great counselors, but my favorite was probably Amare. He was always doing wacky and funny things for us. Miss Vicki always had an open heart and with her friend Amanda, they made me have the most fun I could possibly have.

BAYER

Jivi®
antihemophilic factor
(recombinant) PEGylated-aucl
LET'S GO

JIVI®
ADYNOVATE®

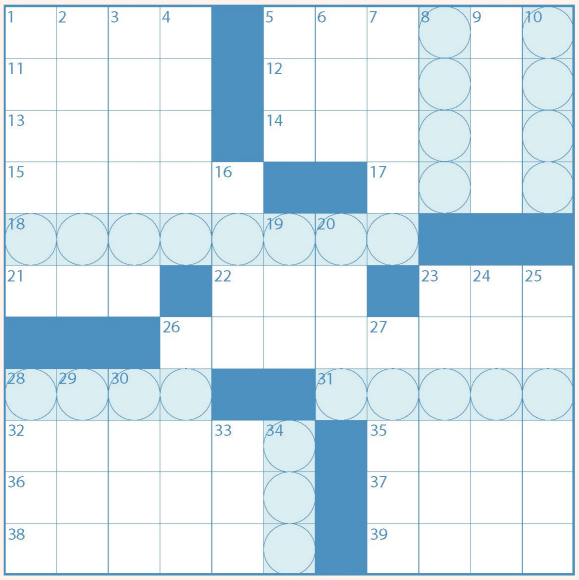
PK (Pharmacokinetics) Study Data

Talk to your doctor about the study.

Scan the QR code to learn more about PK at **UnderstandingPK.com**

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. arose, 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

CLOT Line Assistance Program

Members:

If you are going through a difficult time, please remember, your HBDA family is here for you!

If you have been affected by COVID-19, or if you need assistance due to an unexpected circumstance, please reach out to us.

Leslie Bailey Joins HBDA Board Of Directors

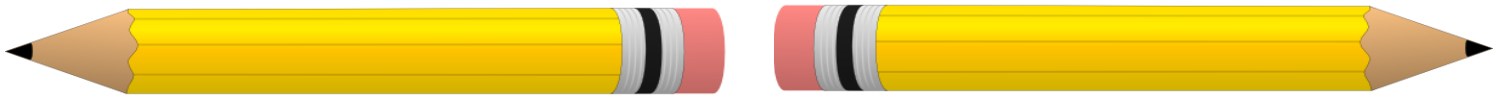
Leslie is a dedicated and personable professional with over 45 years' experience in diverse business arenas. She started her career in broadcasting, working at WSFA TV for over 15 years while also working on the Y-102 Morning Radio Show with Larry Stevens. After marrying Paul Bailey, Jr in 1989, Leslie decided to open her own business, Silver Spoon Caterers and Events. She was a recipient of the "Small Business of the Year Award" in 1992 and in 2003. She received the very first "Arts in Education Award" ever given to a business as well as the "Good Neighbor Award" presented by the Montgomery Junior League.

In 2006, she wrote and edited a national cookbook entitled "Hey Leslie, What's Cooking," published by River City Publishers. This cookbook was a compilation of recipes that she shared with WSFA viewers for over 14 years as well as with the ones she prepared on three Alabama Public Television statewide telethons.

Leslie joined HBDA in 2012 as PR and Marketing Director. Leslie's talent and enthusiasm and offered a fresh dimension to our events and programs. Leslie provided many new avenues for HBDA using her contacts from radio and tv to expand our outreach and to increase community awareness. Leslie was successful in capturing new sources of revenue with foundation grants and new fundraising ventures. In 2017, Leslie was offered a position to further utilize her talents with event planning and she left HBDA to pursue this opportunity. Leslie has, once again, offered her skills and talents and is the newest member of the HBDA Board of Directors. We welcome Leslie's fresh approach and flair back to HBDA and look forward to her involvement in our future endeavors.

Welcome to the Board

HBDA School Supplies Assistance Program



We were so excited to bring back this simple yet rewarding way to help our members out during this crazy season of “Back to School prepping” during tax-free weekend! We were able to help many of our members with Walmart gift cards through our CLOT Line Patient Assistance Program! We love giving back to our members! Thank you for participating and we look forward to bringing this back again next year!

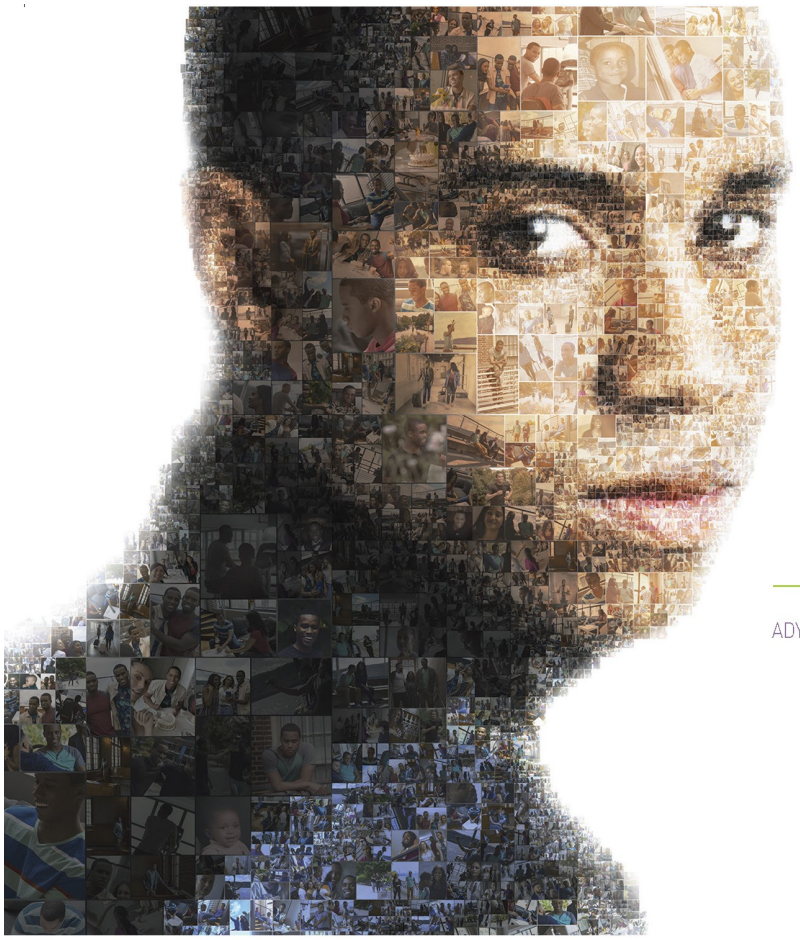
Don't run out of time.

The deadline is fast approaching to make reservations to be a part of HBDA's Weekend of Fellowship and Enlightenment at this year's "Camp Harvest" Family Educational Weekend! October 21-23,2022 at Children's Harbor.

It's a time to catch up on what is happening and what WILL be happening in the world of bleeding disorders, with informative sessions from industry partners and top keynote speakers.

Plus, you will have time to re-connect and bond with your HBDA Family and Industry Representatives.

It is an opportunity to be part of some of HBDA's favorite Fall traditions: Family Portraits, hot chocolate and cider around a roaring campfire, arts and crafts, our annual Family pumpkin carving contest for bragging rights and so much more!



No actual patients depicted.

ADYNOVATE
[Antihemophilic Factor (Recombinant), PEGylated]
REAL LIFE. REAL BLEED PROTECTION.*

HEMOPHILIA A IS A PIECE OF THEM. NOT ALL OF THEM.

ADYNOVATE® has a simple, twice-weekly dosing schedule on the same 2 days every week that can help personalize treatment, so your patients have more time to spend doing the other things that also make them who they are.[1,2]

*In clinical trials, ADYNOVATE demonstrated the ability to help patients prevent bleeding episodes using a prophylaxis regimen.

AdynovateRealLife.com/HCP

ADYNOVATE twice-weekly prophylaxis prevented or reduced the number of bleeds[2]

ADYNOVATE was proven in 2 pivotal clinical trials to prevent or reduce the number of bleeding episodes in children and adults when used regularly (prophylaxis)[2]

- **Children Under 12 Years**: This study evaluated the efficacy of ADYNOVATE twice-weekly prophylaxis and determined the ability to treat bleeding episodes for 6 months in 66 children under 12 years old who received 40–60 IU/kg of ADYNOVATE prophylaxis treatment
  - During the 6-month study in children under 12, those receiving twice-weekly prophylaxis treatment experienced a median† overall ABR‡ of 2.0
  - 0 bleeds in 38% (25 out of 66 patients) during 6 months on twice-weekly prophylaxis
- **Adolescents and Adults 12 Years and Older**: This study evaluated the efficacy of ADYNOVATE in a 6-month study that compared the efficacy of a twice-weekly prophylactic regimen with on-demand treatment and determined hemostatic efficacy in the treatment of bleeding episodes in 137 patients. These adolescents and adults were given either ADYNOVATE prophylaxis twice-weekly at a dose of 40–50 IU/kg (120 patients) or on-demand treatment with ADYNOVATE at a dose of 10–60 IU/kg (17 patients). The primary study goal was to compare ABR‡ between the prophylaxis and on-demand treatment groups[2]
  - 95% reduction in median overall ABR [41.5 median ABR with on-demand (17 patients) vs 1.9 median ABR with prophylaxis (120 patients)]
  - 0 bleeds in 40% (40 out of 101 per-protocol§ patients) during 6 months on twice-weekly prophylaxis

†Median is defined as the middle number in a list of numbers arranged in numerical order.
‡ABR=annualized bleed rate, the number of bleeds that occur over a year
§Per-protocol patients were assigned to the prophylactic group and treated with their originally assigned dose for the entire duration of the study.

ADYNOVATE Important Information

Indications and Limitation of Use

ADYNOVATE is a human antihemophilic factor indicated in children and adults with hemophilia A (congenital factor VIII deficiency) for:

- On-demand treatment and control of bleeding episodes
- Perioperative management
- Routine prophylaxis to reduce the frequency of bleeding episodes

ADYNOVATE is not indicated for the treatment of von Willebrand disease.

DETAILED IMPORTANT RISK INFORMATION

CONTRAINDICATIONS

Prior anaphylactic reaction to ADYNOVATE, to the parent molecule (ADVATE® [Antihemophilic Factor (Recombinant)]), mouse or hamster protein, or excipients of ADYNOVATE (e.g. Tris, mannitol, trehalose, glutathione, and/or polysorbate 80).

WARNINGS & PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions are possible with ADYNOVATE. Allergic-type hypersensitivity reactions, including anaphylaxis, have been reported with other recombinant antihemophilic factor VIII products, including the parent molecule, ADVATE. Early signs of hypersensitivity reactions that can progress to anaphylaxis may include angioedema, chest tightness, dyspnea, wheezing, urticaria, and pruritus. Immediately discontinue administration and initiate appropriate treatment if hypersensitivity reactions occur.

WARNINGS & PRECAUTIONS (continued)

Neutralizing Antibodies

Formation of neutralizing antibodies (inhibitors) to factor VIII can occur following administration of ADYNOVATE. Monitor patients regularly for the development of factor VIII inhibitors by appropriate clinical observations and laboratory tests. Perform an assay that measures factor VIII inhibitor concentration if the plasma factor VIII level fails to increase as expected, or if bleeding is not controlled with expected dose.

ADVERSE REACTIONS

The most common adverse reactions (≥1% of subjects) reported in the clinical studies were headache, diarrhea, rash, nausea, dizziness and urticaria.

Please see the following page for the Brief Summary of the ADYNOVATE Full Prescribing Information.

For Full Prescribing Information, visit www.adynovatepro.com.

References: 1. Valentino LA. Considerations in individualizing prophylaxis in patients with haemophilia A. *Haemophilia.* 2014;20(5):607-615. **2.** ADYNOVATE Prescribing Information.

Takeda

ADYNOVATE [Antihemophilic Factor (Recombinant) PEGylated] **Rx Only**
Lyophilized Powder for Reconstitution for Intravenous Injection
BRIEF SUMMARY: Consult the Full Prescribing Information for complete product information.

INDICATIONS AND USAGE

ADYNOVATE is a human antihemophilic factor indicated in children and adults with hemophilia A (congenital factor VIII deficiency) for:

- On-demand treatment and control of bleeding episodes
- Perioperative management
- Routine prophylaxis to reduce the frequency of bleeding episodes

Limitation of Use

ADYNOVATE is not indicated for the treatment of von Willebrand disease.

CONTRAINDICATIONS

ADYNOVATE is contraindicated in patients who have had prior anaphylactic reaction to ADYNOVATE, to the parent molecule (ADVATE), mouse or hamster protein, or excipients of ADYNOVATE (e.g. Tris, mannitol, trehalose, glutathione, and/or polysorbate 80).

WARNINGS and PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions are possible with ADYNOVATE. Allergic-type hypersensitivity reactions, including anaphylaxis, have been reported with other recombinant antihemophilic factor VIII products, including the parent molecule, ADVATE. Early signs of hypersensitivity reactions that can progress to anaphylaxis may include angioedema, chest tightness, dyspnea, wheezing, urticaria, and pruritus. Immediately discontinue administration and initiate appropriate treatment if hypersensitivity reactions occur.

Neutralizing Antibodies

Formation of neutralizing antibodies (inhibitors) to factor VIII can occur following administration of ADYNOVATE. Monitor patients regularly for the development of factor VIII inhibitors by appropriate clinical observations and laboratory tests. Perform an assay that measures factor VIII inhibitor concentration if the plasma factor VIII level fails to increase as expected, or if bleeding is not controlled with expected dose.

Monitoring Laboratory Tests

- Monitor plasma factor VIII activity by performing a validated one-stage clotting assay to confirm the adequate factor VIII levels have been achieved and maintained.
- Monitor for the development of factor VIII inhibitors. Perform the Bethesda inhibitor assay to determine if factor VIII inhibitor is present. If expected factor VIII activity plasma levels are not attained, or if bleeding is not controlled with the expected dose of ADYNOVATE, use Bethesda Units (BU) to determine inhibitor levels.

ADVERSE REACTIONS

The most common adverse reactions (≥1% of subjects) reported in the clinical studies were headache, diarrhea, rash, nausea, dizziness and urticaria.

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in clinical trials of another drug and may not reflect the rates observed in practice.

The safety of ADYNOVATE was evaluated in 365 previously treated patients (PTPs) and previously untreated patients (PUPs) with severe hemophilia A (factor VIII less than 1% of normal), who received at least one dose of ADYNOVATE in 6 completed multi-center, prospective, open label clinical studies and 1 ongoing clinical study. The total number of infusions within the safety database is 74487. Following are the adverse reactions reported during clinical studies.

Adverse reactions reported for ADYNOVATE as shown by Percent of Subjects, Number of subjects (%, n) (N=365). Reported adverse reactions are listed by MedDRA Preferred Term. Diarrhea (6.8%, n=25), Nausea (2.2%, n=8), Ocular Hyperaemia (0.8%, n=3), Hypersensitivity[a] (0.5%, n=2), Headache (11.2%, n=41), Dizziness (1.9%, n=7), Rash (2.7%, n=10), Urticaria (1.9%, n=7), Drug Eruption (0.3%, n=1), Flushing (0.27%, n=1), Eosinophil Count Increased (0.5%, n=2), Infusion Related Reaction (0.5%, n=2).

[a] The event of hypersensitivity was a mild transient non-serious rash, occurring in one 2-year old patient who had developed a previous rash while on ADYNOVATE.

Two cases of acute pancreatitis, with no precipitating cause identified in one case, were reported in adults during an extension study of the clinical trial which evaluated 216 subjects. Administration of ADYNOVATE continued and both cases resolved.

Immunogenicity

Clinical trial subjects were monitored for neutralizing (inhibitory) antibodies to FVIII. Of the 6 completed clinical trials in previously treated patients (PTPs), in the randomized controlled trial comparing different dosing regimens of ADYNOVATE, one previously treated patient developed a transient low titer FVIII inhibitor at 0.6 BU while receiving more frequent dosing with ADYNOVATE. In a continuation study with ADYNOVATE, one patient developed a transient low titer (0.6 BU) FVIII inhibitor. Repeat testing did not confirm the presence of inhibitor. Both of these subjects continued treatment without change in the dose of ADYNOVATE.

Immunogenicity also was evaluated by measuring the development of binding IgG and IgM antibodies against factor VIII, PEGylated (PEG)-factor VIII, PEG and Chinese hamster ovary (CHO) protein using validated ELISA assays.

Persistent treatment-emergent binding antibodies against FVIII, PEG-FVIII or PEG were not detected. Out of 365 subjects, thirty-six subjects in total showed pre-existing antibodies to factor VIII (n=5), PEG-factor VIII (n=31) and/or PEG (n=6) prior to the first exposure to ADYNOVATE. Twenty-four subjects who tested negative at screening developed transient antibodies against factor VIII (n=10), PEG-FVIII (n=16) and/or PEG (n=3) at one or two consecutive study visits. Antibodies were transient and not detectable at subsequent visits. Two subjects showed positive results for binding antibodies at study completion or at the time of data cutoff. Binding antibodies that were detected prior to exposure to ADYNOVATE, that transiently developed during the trial or were still detectable at study completion or data cutoff could not be correlated to any impaired treatment efficacy or altered PK parameters. There was no causal relationship between observed adverse events and binding antibodies except in one subject where a causal relationship cannot be ruled out based on available data. No subject had pre-existing or treatment-emergent antibodies to CHO protein.

From an ongoing study in previously untreated patients <6 years with severe hemophilia A, 9 cases of FVIII inhibitor development associated with treatment with ADYNOVATE were reported.

The detection of antibodies that are reactive to factor VIII is highly dependent on many factors, including: the sensitivity and specificity of the assay, sample handling, timing of sample collection, concomitant medications and underlying disease. For these reasons, comparison of the incidence of antibodies to ADYNOVATE with the incidence of antibodies to other products may be misleading.

USE IN SPECIFIC POPULATIONS

Pregnancy: Risk Summary

There are no data with ADYNOVATE use in pregnant women to inform a drug-associated risk. Animal reproduction studies have not been conducted with ADYNOVATE. It is unknown whether ADYNOVATE can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. In the U.S. general population, the estimated background risk of major birth defect and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Lactation: Risk Summary

There is no information regarding the presence of ADYNOVATE in human milk, the effect on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ADYNOVATE and any potential adverse effects on the breastfed infant from ADYNOVATE or from the underlying maternal condition.

Pediatric Use

Safety and efficacy studies have been performed in 91 previously treated, pediatric patients age 1 year to <18 years who received at least one dose of ADYNOVATE as part of routine prophylaxis, on-demand treatment of bleeding episodes, or perioperative management. Adolescent subjects age 12 to <18 (n=25) were enrolled in the adult and adolescent safety and efficacy trial, and subjects <12 years of age (n=66) were enrolled in a pediatric trial. The safety and efficacy of ADYNOVATE in routine prophylaxis and the treatment of bleeding episodes were comparable between children and adults. Pharmacokinetic studies in children (<12 years) have demonstrated higher clearance, a shorter half-life and lower incremental recovery of factor VIII compared to adults. Because clearance (based on per kg body weight) has been demonstrated to be higher in children (<12 years), dose adjustment or more frequent dosing based on per kg body weight may be needed in this population.

Geriatric Use

Clinical studies of ADYNOVATE did not include subjects aged 65 and over.

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HBDA Information

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Birthday Blessings

August

Amy Blair
Terrell Abrams
Jacob Weaver
Kaitlyn Weaver
Rachel Cooper-Leal
Dylan Ward
Rocisa Banks
Tikila Hawthorne
Shelia Baird
Rick Dinkins
Kristopher Lewis
Cannan Dickinson
Tara Gerling
Mackenzie Jones
Bella Dickinson
Jeannie McLaughlin
Tim Mason
Ajie Attawia
Heeyeon Chung
Belita Abrams
Christian Blyden
Kileeann Warren
Bethalyn Bailey
Makenzie Clarke
Jeannie Dickerson
Robert Bate
Ericka Caro
VaShette Davis
Chris Blair

September

Ayden Hoggle
Madison Kelley
Jaxson Kelley
Jared McLaughlin
Lyric Donahoo
Jessica Ward
Zachary Pressley
Mark Osborne
Jasmine Hoggle
Larry Grammer
Brayden Cooper
NyAnnah Davis
Mary Hunter
John Masline
Erica Goss
Jaymee Vowell
Cooper Guadalupe
Vicki Jackson
Kristen Blair
Chesca Barnett
Abi Dickinson
Lee Hall
Jace McLaughlin
Raley Hoggle
Kristy Roberts
Jennifer Mason

October

Scott Weaver
Pat White
Caelum Walls
Nicole Lloyd
Levi McLaughlin
Luke Bradshaw
Chance Abrams
Blake Morgan
Joshua Sorrells
Katelyn Erben
Christian Pressley
Micah Champagne
Justin Clarke
Harper Walls
Jonathan Hall
Fallon Howard
Adam Bradshaw
Jennifer Harris
Jason Kelley
Andy Hall
Tisha Ward
Ethan Fields