

HBDA QUARTERLY NEWSLETTER

Fall Edition 2018

Rick Dinkins, Chairman

Volume 39

Vicki Jackson, Executive Director

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Hemophilia and Bleeding
Disorders of Alabama, Inc.

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Camp Harvest 2018 October 26 - 28 Children's Harbor Lodge



HBDA's 2018 Camp Harvest was full of new twists. With a new app, new Youth Ambassador program and new Saturday night activities that focused on family, it was a fabulous weekend.

Friday night kicked off with the introduction of a new app, Yapp, that kept everyone up to date with real time notifications. Yapp was not only helpful as staff was able to post changes to the schedule, but it also allowed members and staff to post comments and photos.

HBDA CAMP HARVEST

Camp Harvest started off with a delicious dinner of chili, and chicken and dumplings. Afterwards, the industry sponsors welcomed everyone with educational presentations and informative exhibit booths. The fun began with an outdoor movie at the amphitheater hosted by Hyundai Manufacturing Company. Colburn Keenan Foundation hosted a campfire by the waterfront with hot apple cider and cocoa to help everyone keep warm. After a hearty breakfast on Saturday morning, the educational sessions began. While the adults and teens enjoyed presentations from the sponsors, the kids had their own programming filled with making yogurt parfaits that represented blood clotting and fall themed arts and crafts.

Deputy Dennis Hill with the Elmore County Sheriff's Department joined us at camp this year with a presentation on anti-bullying. Deputy Hill also had a presentation focused around leadership skills for the Youth Ambassadors program that kicked off this year. HBDA was very honored and excited to welcome Deputy Hill to Camp Harvest and to our organization.



HBDA CAMP HARVEST

As the educational sessions ended, Camp Harvest transformed into an exciting family festival hosted by HBDA. There were many activities for every age to enjoy. With popcorn and caramel apples, bouncy houses and spin rides, arts and crafts and a petting zoo, everyone had a great time.

To finish out the family fun for the day, HBDA hosted a "Minute to Win It" game night. The summer campers were especially excited when the competition began. With two overflowing baskets of family prizes up for grabs, the competition was fierce. Everyone seemed to have so much fun.

HBDA was pleased to welcome Dr. Tami Singleton to Camp Harvest again this year. Her presentation on inhibitors and the importance of pharmacokinetics was informative, energetic and engaging.

As Camp Harvest came to a close, the Peer to Peer discussion reminded the older generation of how far they have come and enlightened the younger generation on how much better treatments and therapies are now. This time of encouragement and discussion reminds us that the bleeding disorders community truly is a family, "Because no one bleeds alone."



CAMP HARVEST MEMBER TESTIMONY

Yesterday was awesome. Perfect weather, the festivities....5 stars.

Kids loved everything. The arts and crafts, petting zoo, blow ups, caramel apples, ride...everything. The trick or treat with carnival inside was really special. And the family night...a good good time cheering and watching.

I know it took a lot of work and commitment and it showed. We really appreciate the work y'all do and the vendors.

Every year you guys surprise us in how good this is and once again you topped yourselves. And the carnival dinner with corn dogs was fun too. Hugs and kisses and many thanks!

The crew in 7C
-Chesca Barnett and Family



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WORDS FROM THE CHAIR

Happy Holidays and Merry Christmas!

Hope you all had a bountiful Thanksgiving ...I did! Debby's in the throes of Christmas decorating and I'm serving as her labor for the outside wreaths and lighting....gotta love it!

Recapping the fall and looking to the rest of 2018... October's Camp Harvest was a resounding success. You probably noticed that there were fewer "big" activities at this year's fall event as the staff wanted to focus more on quality of programming and activities rather than the quantity. I think it served everyone much better and allowed plenty of time for the traditional activities everyone enjoys. I personally thought the speakers were the best we've had during my tenure on the board.

Vicki and Amanda put the final details together for a wonderful Year End Luncheon on December 8th in Montgomery. Be on the lookout for a recap of this event in the next newsletter.

2018 has been a great year for HBDA. This year has seen several changes in our organization...new office location, redesigned website, increased use of technology to increase efficiency in the day-to-day operations, and more. Camp Clot Not and the Annual Meeting were very successful as was our annual golf tournament. I continue to see improvements in the planning and operations for the future as we move to take this organization to another level of support for you and to you.

Stays tuned for more information regarding the 2019 Annual Meeting, but, in the mean time, enjoy your holidays, be safe and be a blessing in someone's life.

Rick Dinkins



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CHILDREN'S HARBOR DONATION

HBDA has been blessed to be given the opportunity to use the donated facilities at Children's Harbor on Lake Martin for many years now. Throughout that time, we have seen Children's Harbor grow and serve many different camps and organizations. They are always willing to help in any way possible to make sure that every camp's experience is a great one.

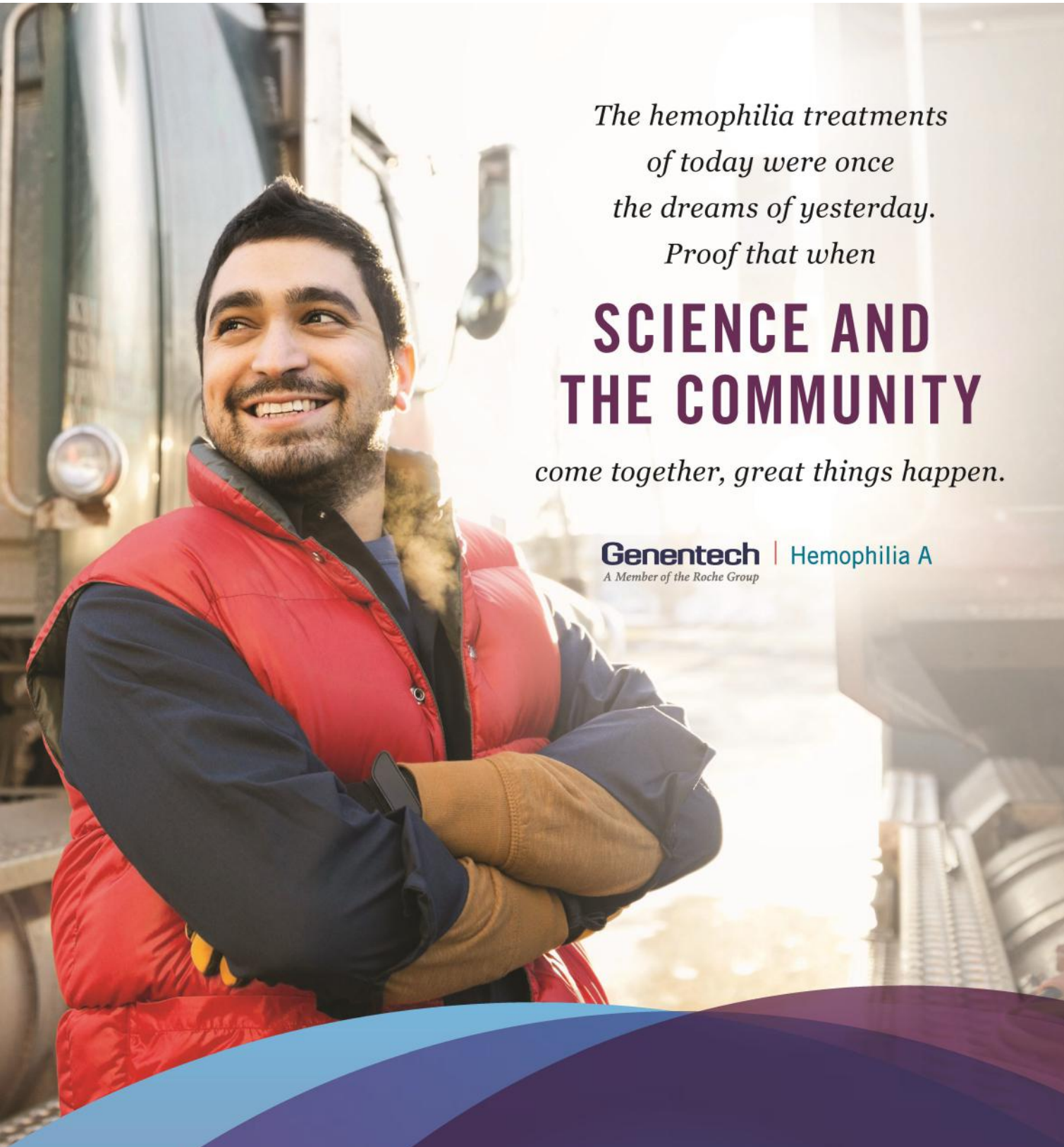
This year, with a grant from the Colburn Keenan Foundation, HBDA was able to give back to Children's Harbor. We took notice of a need for new life jackets, especially in certain sizes, at our summer camp, Camp Clot Not last summer. With the funds given from the grant, HBDA was able to purchase around 100 new life jackets to donate to Children's Harbor.

Thank you to Children's Harbor for all of your support and for your partnership with HBDA. We truly love working with you and we hope that this partnership can continue for many years.

Thank you to Colburn Keenan for the grant opportunity to be able to support such an incredible organization!



Colburn  Keenan Foundation, Inc.®



*The hemophilia treatments
of today were once
the dreams of yesterday.*

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come together, great things happen.

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Let's put science to work

HBDA ANNUAL MEETING 2019

Be on the lookout for more information
regarding the location of the 2019 Annual
Meeting on the HBDA website!

Date: April 26 - 28, 2019



Hemophilia and Bleeding
Disorders of Alabama, Inc.

2019 UPCOMING EVENTS AND DATES

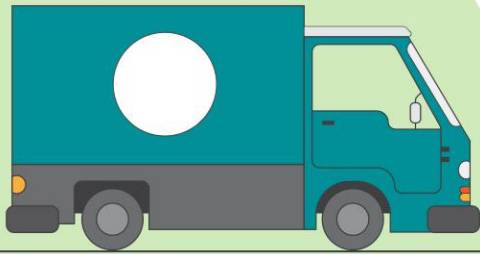
April 26 - 28, 2019	HBDA Annual Meeting	Location TBD
June 15 - 20, 2019	Camp Clot Not	Children's Harbor
September 2019	Golf Tournament	Robert Trent Jones
October 25 - 27, 2019	Camp Harvest	Children's Harbor
December 7, 2019	Year End Luncheon	Location TBD



MARK YOUR CALENDARS!

URGENT ANNOUNCEMENT!

HBDA has moved to a **NEW LOCATION!!!!**



WE'VE MOVED

Our NEW ADDRESS is:

917 W Osceola Street

Wetumpka, AL 36092

Our phone number remains: (334) 478-7822

Our fax number remains: (334) 478-7824



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ADYNOVATE

[Antihemophilic Factor
(Recombinant), PEGylated]

ADYNOVATE® is FDA approved for children and adults with Hemophilia A

PROVEN PROPHYLAXIS +
SIMPLE,* TWICE-WEEKLY DOSING SCHEDULE =

moments **YOUR WAY**

*ADYNOVATE allows you to infuse on the same 2 days every week. Work with your doctor to determine an infusion schedule that is appropriate for you.

The pediatric study of children <12 years of age (N=66) evaluated the immunogenicity, efficacy, PK (as compared to ADVATE® [Antihemophilic Factor (Recombinant)]), and safety of ADYNOVATE twice-weekly prophylaxis (40-60 IU/kg) and determined hemostatic efficacy in the treatment of bleeding episodes for 6 months.^{1,2}

The pivotal trial of children and adults ≥12 years (N=137) evaluated the efficacy, PK, and safety of ADYNOVATE twice-weekly prophylaxis (40-50 IU/kg) vs on-demand (10-60 IU/kg) treatment, and determined hemostatic efficacy in the treatment of bleeding episodes for 6 months.¹

†Children (<12 years) experienced a median overall ABR of 2.0 (IQR: 3.9) and a median ABR of zero for both joint (IQR: 1.9) and spontaneous (IQR: 1.9) bleeds.¹

‡38% (n=25) of children (<12 years) experienced zero total bleeds; 73% (n=48) experienced zero joint bleeds; and 67% (n=44) experienced zero spontaneous bleeds.¹

Talk to your doctor to see if ADYNOVATE treatment may be right for you and visit ADYNOVATE.com

ADYNOVATE [Antihemophilic Factor (Recombinant), PEGylated] Important Information

What is ADYNOVATE?

- ADYNOVATE is an injectable medicine that is used to help treat and control bleeding in children and adults with hemophilia A (congenital Factor VIII deficiency).
- Your healthcare provider (HCP) may give you ADYNOVATE when you have surgery.
- ADYNOVATE can reduce the number of bleeding episodes when used regularly (prophylaxis).

ADYNOVATE is not used to treat von Willebrand disease.

DETAILED IMPORTANT RISK INFORMATION

Who should not use ADYNOVATE?

Do not use ADYNOVATE if you:

- Are allergic to mice or hamster protein
- Are allergic to any ingredients in ADYNOVATE or ADVATE [Antihemophilic Factor (Recombinant)]

Tell your HCP if you are pregnant or breastfeeding because ADYNOVATE may not be right for you.

What should I tell my HCP before using ADYNOVATE?

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

What important information do I need to know about ADYNOVATE?

- You can have an allergic reaction to ADYNOVATE. 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.
- Do not attempt to infuse yourself with ADYNOVATE unless you have been taught by your HCP or hemophilia center.

What else should I know about ADYNOVATE 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 ADYNOVATE 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 ADYNOVATE?

- The common side effects of ADYNOVATE are headache and nausea. These are not all the possible side effects with ADYNOVATE. Tell your HCP 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 Important Facts about ADYNOVATE on the following page and discuss with your HCP.

For full Prescribing Information, visit www.ADYNOVATE.com.

References: 1. ADYNOVATE Prescribing Information. 2. Mullins ES, Stasyshyn O, Alvarez-Román MT, et al. Extended half-life pegylated, full-length recombinant factor VIII for prophylaxis in children with severe haemophilia A. *Haemophilia*. 2016 Nov 27. doi: 10.1111/hae.13119 [Epub ahead of print]. 3. Data on file.



Patient Important facts about

ADYNOVATE® [Antihemophilic Factor (Recombinant), PEGylated]

This leaflet summarizes important information about ADYNOVATE. 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 ADYNOVATE. If you have any questions after reading this, ask your healthcare provider.

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

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 ADYNOVATE so that your treatment will work best for you.

What is ADYNOVATE?

ADYNOVATE is an injectable medicine that is used to help treat and control bleeding in children and adults with hemophilia A (congenital Factor VIII deficiency). Your healthcare provider may give you ADYNOVATE when you have surgery. ADYNOVATE can reduce the number of bleeding episodes when used regularly [prophylaxis].

ADYNOVATE is not used to treat von Willebrand disease.

Who should not use ADYNOVATE?

You should not use ADYNOVATE if you:

- Are allergic to mice or hamster protein
- Are allergic to any ingredients in ADYNOVATE or ADVATE® [Antihemophilic Factor (Recombinant)]

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

How should I use ADYNOVATE?

ADYNOVATE is given directly into the bloodstream.

You may infuse ADYNOVATE 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 ADYNOVATE by themselves or with the help of a family member.

Your healthcare provider will tell you how much ADYNOVATE to use based on your individual weight, level of physical activity, the severity of your hemophilia A, and where you are bleeding.

Reconstituted product (after mixing dry product with wet diluent) must be used within 3 hours and cannot be stored or refrigerated. Discard any ADYNOVATE left in the vial at the end of your infusion as directed by your healthcare professional.

You may have to have blood tests done after getting ADYNOVATE to be sure that your blood level of factor VIII is high enough to clot your blood.

How should I use ADYNOVATE? (cont'd)

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

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

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

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The common side effects of ADYNOVATE are headache and nausea. 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 ADYNOVATE. You can ask your healthcare provider for information that is written for healthcare professionals.

What else should I know about ADYNOVATE 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 ADYNOVATE 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 ADYNOVATE for a condition for which it is not prescribed. Do not share ADYNOVATE 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 ADYNOVATE. The FDA-approved product labeling can be found at www.shirecontent.com/PI/PDFs/ADYNOVATE_USA_ENG.pdf or 855-4-ADYNOVATE.

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.

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We wish our members, sponsors, and volunteers a Merry Christmas and a prosperous New Year! Thank you for all of your support of HBDA in 2018 and we look forward to growing together in 2019!

Sincerely,
The Staff and Board of HBDA

NOW APPROVED

FOR PEOPLE WITH HEMOPHILIA A WITH OR WITHOUT FACTOR VIII INHIBITORS

GO SEEK. GO EXPLORE. GO AHEAD.



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What is HEMLIBRA?

HEMLIBRA is a prescription medicine used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children, ages newborn and older, with hemophilia A with or without factor VIII inhibitors.

What is the most important information I should know about HEMLIBRA?

HEMLIBRA increases the potential for your blood to clot. Carefully follow your healthcare provider's instructions regarding when to use an on-demand bypassing agent or factor VIII, and the dose and schedule to use for breakthrough bleed treatment. HEMLIBRA may cause serious side effects when used with activated prothrombin complex concentrate (aPCC; FEIBA®), including thrombotic microangiopathy (TMA), and blood clots (thrombotic events). If aPCC (FEIBA®) is needed, talk to your healthcare provider in case you feel you need more than 100 U/kg of aPCC (FEIBA®) total.

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


HEMLIBRA
emicizumab-kxwh 150
injection for subcutaneous use 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

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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



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Fax: (334) 478-7824

Website: www.hbda.us

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BIRTHDAY BLESSINGS

November

Anthony Holland
Grace Hall
Brynlee White
Katie Lee
Cameron Jones
Casey Sanders
Laura Pitman
Trace Lee
Chelynn Pargo
Robin Blair
Blake Romaine
Brayden Botts
Quintez Renfroe
Patsy Lewis
Makaylie Kelley
Grace Chung
Ciara Pargo
Charlie Hoover
Jason Branch
Alexandra Hall
Fantine Martin
Ed Leathers
Michael King
Brent White

December

Landry Camp
Joseph Clarke
Mary Cathrine Noa
Shelia Vickery
Silas Lee
Tricia Watts
Debby Dinkins
Paul Moore
Mark Fitzgerald
Camdyn Pressley
Kimberly Wood
Daniel Botts
Dawson Findley
Joseph King
Karen Hallford
Travis Reed
Amanda Jennings
Ashley Smith
Leslie Bailey
Travis Todd
Kelly Champagne

January

Madilynn Clarke
Nathan Sanders
Mary Beth Clarke
David Hall
Marcus Chung
Robert Masline
Jayla Lewis
Amare Banks
Takiya Wells
Jason Blair
Josh Allen
Bentley Golden
Lauren Kilgore
Donna Bate
Brayden Crenshaw
Bryan Utterback
Daelynn Romaine
Maria Hall
Jeremy Jones
Angel Jones