Fall 2015

KHF Hemosphere

"Camp Discovery" KHF Summer Camp

Once again, the KHF Summer Camp Program for youths with bleeding disorders and their siblings was a successful, fun-filled educational and recreational experience for thirty-four children and teens from all parts of our state. Our summer camp takes place every July at Cedar Ridge Camp in Jefferson County The focus of our summer camp is to provide an opportunity for youths who are living with a chronic condition to be 1) active in a traditional camp setting and interact with other youngsters who are dealing with the same health issues, 2) learn to manage their disorder which includes sticking themselves to administer their clotting factor replacement and develop a healthy lifestyle, and 3) have loads of fun just as any other kids would have at summer camp.

Activities included swimming and more swimming, building bird houses, zip lining, navigating the team challenge course, bowling, amazing race and scavenger hunt, and playing their favorite game of capture the flag. The cultural enrichment component featured the state of Kentucky this year complete with a fried chicken dinner, "horse racing," and a lively performance by the Kentucky Home Cloggers.

The KHF volunteer camp staff consists of a seasoned and enthusiastic camp director and dedicated counselors, guest facilitators, complemented by credentialed and experienced nurses. We thank the camp staff for providing a safe camp environment along with educational and recreational activities that were enjoyed by all campers. Camp was made possible with support from Kosair Charities, Baxalta, WHAS Crusade for Children, Pfizer, CSL Behring, Novo Nordisk, Option Care, Bayer HealthCare, Accredo, and Grifols.

Infusion of Humanitarian Aid to Help Sustain Hemophilia Treatment in Developing World

The World Federation of Hemophilia (WFH) and its Humanitarian Aid Program announce an international pledge of donated hemophilia therapies, which is unprecedented in size. The donation will provide 500 million international units (IUs) of critically needed hemophilia therapy over a five-year span.

This initial wave of donations, currently arriving at hemophilia treatment centers across the globe, represent the first phase of an overall 10-year commitment made by Biogen and Swedish Orphan Biovitrum AB (Sobi) to generate 1 billion IUs of hemophilia therapies for humanitarian use. The countries currently receiving aid include Senegal, Kenya, Philippines, Dominican Republic, Uzbekistan, Jordan, Egypt, Morocco, Pakistan, El Salvador, Indonesia, Ghana, Myanmar, India, Sri Lanka and Nigeria.

The Humanitarian Aid Program was established in 1996 to provide treatment and care for individuals with hemophilia in the developing world, where the scarcity of adequate healthcare and sustained factor product supplies is felt most acutely. According to WFH, of the estimated 400,000 hemophilia patients worldwide, 300,000 live in places where there is little-to-no access to viable diagnosis, treatment and management. In such an environment, quality of life is severely diminished for people with bleeding disorders and life-threatening situations are more common.

> ***"…we may now be in a position to create a foundation for more sustainable and improved care in parts of the world where there is an urgent need"***

"The majority of people with hemophilia in developing countries do not live past adulthood and if they do, they face a life of severe disability and chronic pain," said Assad E. Haffar, MD, WFH Humanitarian Aid Program Director. "The lack of access to clotting factor concentrates in these countries presents an urgent and important public health challenge."

"By expanding the WFH Humanitarian Aid Program through larger and more predictable donations, we may now be in a position to create a foundation for more sustainable and improved care in parts of the world where there is an urgent need," said WFH President Alain Weill.

To learn more about WFH's Humanitarian Aid Program go to: **www.wfh.org**.

Source: *Joint press release from WFH, Biogen and Sobi dated October 12, 2015*

MASAC Releases New Recommendation on Inhibitors In Light of CDC Findings

The National Hemophilia Foundation's (NHF's) Medical and Scientific Advisory Council (MASAC) recently issued a new recommendation concerning inhibitor testing and surveillance for patients with hemophilia A and B. MASAC Document #236, adopted by NHF's Board of Directors on October 6, 2015, was created in response to significant findings from the US Centers for Disease Control and Prevention's (CDC's) Hemophilia Inhibitor Research Study (HIRS).

A six-year-long research initiative, HIRS was designed to assess the feasibility and utility of conducting national monitoring for inhibitors among people with hemophilia living in the US. A total of 1,163 patients with hemophilia from 17 US-based hemophilia treatment centers (HTCs) were enrolled and subsequently monitored for up to 6 years to establish the optimal way to determine who was at risk for developing an inhibitor.

In light of the results, investigators concluded the following:

- All people with hemophilia, regardless of age, are at risk for developing inhibitors
- One-third of newly-developed inhibitors were found in people with non-severe hemophilia
- One-half were older than 5
- One-quarter had used infused factor for more than 150 days
- Six out of 10 people with hemophilia with an inhibitor had no symptoms
- Regular screening of people with hemophilia for early detection of an inhibitor by the CDC laboratory is feasible, and will inform efforts to measure rates of this complication

The results prompted CDC to enhance its surveillance system to include inhibitor testing, to address cost-related barriers to the screening process and establish a standardized testing approach to be employed by all participating HTCs.

In response to CDC's findings, MASAC created a document that includes a series of specific recommendations relevant to lab testing, standardization of an inhibitor screening method, surveillance, inhibitor prevention, research and consumer/provider education.

For details, go to: https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations/MASAC-Recommendations-on-Standardized-Testing-and-Surveillance-for-Inhibitors-in-Patients-with-Hemophilia-A-and-B

Source: *NHF, November 10, 2015*

Event News

Golf Scramble

This year's KHF Golf Scramble took place on June 29th at Oxmoor Country Club, one of Louisville's most popular golf courses. Even a robust afternoon shower did not dampen our players' spirits. Team winners were Paragon Healthcare, 1st place; CSL Behring, 2nd place; and Octapharma, 3rd place. Brian Stentz won the putting contest, and Pamela Price's lucky ball won the Ball Drop. Our junior volunteers who sold special score boosters to the golfers in support of the KHF Summer Camp that they attend every year won the hearts of all event participants. The three young ladies raised $463, which was generously matched by a $1,000 donation from Kosair Charities.

Team sponsors were Accredo, Baxalta, Bayer HealthCare, BioRx, CSL Behring, Cottrill's Pharmacy, CVS Caremark, Kosair Charities, Novo Nordisk, Octapharma, Paragon Healthcare, Pfizer, and Republic Bank. Individual player and tee sign sponsors were Accredo, Amerimed, Louisville Oral Surgery and Dental Implants, and Option Care. The event raised $28,000 for KHF's programs and services. We thank all sponsors, donors, planning committee members, and event volunteers for helping us put on a successful event.

Event News

Summer Family Event/ Annual Education Meeting and Walk Kick-Off

The Seelbach Hilton Hotel once again proved to be a fitting venue among our attendees to enjoy nationally known speakers, who addressed hemophilia care and overall wellness topics, a lovely breakfast and Walk Kick-Off lunch, door prizes, and exhibitor product and services information. In the meantime, volunteers from Christian Fellowship facilitated the children's program. After the educational segments and a well-deserved lunch, families enjoyed interactive exhibits, a 3-D Harry Potter movie, and a greatly expanded children's play area at the Kentucky Science Center. Exhibitors and speaker sponsors who helped support this event were Accredo, Baxalta, Biogen, Cottrill's Pharmacy, Inc., CSL Behring, CVS Caremark, Grifols, Matrix Health, Novo Nordisk, Octapharma, Paragon Healthcare, Pfizer, and Option Care

Scholarship Awards

KHF made two post-secondary education scholarship awards for the fall 2015 semester. Eligible applicants for our scholarships are Kentucky residents or individuals who receive treatment in Kentucky who have a bleeding disorder and their immediate family members. We award up to (4) $500 scholarships per year. The Herb Schlaughenhoupt, Jr. Memorial Scholarship was awarded to Andrew Harmon of Bedford, Kentucky. Andrew is a recent high school graduate with a 3.6 GPA. Andrew has been accepted to Jefferson County Community & Technical College where he will be pursuing an Associate's degree in Education with a minor in Computer Science.

The Terry D. Turner Memorial Scholarship was awarded to Alicia Bibelhauser of Versailles, Kentucky. Alicia is also a recent high school graduate with a 3.4 GPA. Alicia has been accepted to Morehead State University, where she plans to major in psychology and work toward a Bachelor's degree. KHF congratulates both scholarship recipients and wishes them well in their educational pursuits.

Note: The scholarship application deadline for the 2016 spring semester is January 15, 2016. Application form and guidelines can be obtained by contacting KHF at 502-456-3233, 800-582-CURE (2873) or by sending an email to info@kyhemo.org.

More News

Kentucky Hemophilia Foundation News and Updates

Board Member Recognition and Welcome

Outgoing board members who were recognized for their board service were Lindsay Martin, Rebecca Daigrepont, and Melissa Hitt. Lindsay served as President for two years, VP two years, and Treasurer for two and a half years. She also was Co-Chair of the Vegasville Planning Committee for several seasons. Lindsay's expertise, guidance, and support are appreciated and will be missed. Rebecca Daigrepont served as Treasurer for two years and Secretary for two years. She also served on the Camp Committee. She was instrumental in securing Wetherby Park in Middletown as our Walk site. Melissa Hitt served as Secretary for one year and as Co-Chair of the Vegasville Planning Committee for several years. Melissa always offers her energy and creativity to enhance our events, especially and foremost Vegasville.

New board members elected are Barb Bitter, Sara Ceresa, and Brad Comer. Barb works for Ricoh as an Enterprise Project Manager. She has a Bachelor of Science degree in Marketing from the University of Kentucky and extensive background in finance, sales, marketing, and training. Sara is a very active volunteer and homemaker with a Bachelor's degree in Chemistry and Biology from Wartburg College in Iowa and graduate training in Genetics from the University of Iowa. She worked as a Clinical Research Coordinator for Dean McGee Eye Institute and held several positions as a Clinical Research Assistant. Her lovely twin daughters attended our summer camp this past year. Brad is a Vice President and Senior Investment Officer at Republic Bank, where he has worked for the past 10 years. He has a Master's degree in Business, a Bachelors degree in Accounting, and a Bachelors degree in Business.

In Memory

July 1, 2015 — October 31, 2015

Gone from our sight but never our memories; gone from our touch but never our hearts…

Sean Bennett
Donna Fleming

William L. Farmer, Sr.
Mrs. William L. Farmer, Sr.
Mrs. William L. Farmer, Sr.

Joe Hardman
Debby & Robert Adams
Teresa English
Donald L. Mattingly
James C. & Rev. Iva Gail McDonnell
Allison & Ernest Noe
James P. Pike

James & Deanna Ray
Janet M. Young

Donald Hester
Donna Fleming

Kentucky Hemophilia Foundation Ninth Annual Fund Drive

We thank the following individuals and companies for their generous support of the 2014– 2015 Annual Fund Drive

Challenge Gift, $25,000
Forcht Bancorp,
Mr. & Mrs. Terry Forcht

Fundraisers Toward Meeting the Challenge, $10,000+
Various Corporate Solicitations, Sales
5th Annual KHF Strides for a Cure
Relay Team Challenge

Forcht Challenge Donors, $1,000 – $2,000+
Donald L. Mattingly
Chevron Humankind
Matching Employee Funds
Nancy Cutrell,
7th Annual Kickathon
in memory of
Terry D. Turner
Mead Johnson Foundation Employee
Engagement Fund
The Community Foundation of Louisville
Made possible by the Zoeller Company

Donors, $250 – $450
Baxter International Foundation
David Hasch
Poynter Family Fundraiser
William H. Shontee
The Webb Family
in honor of Isaac Webb

Donors, $175 – $200
Biogen
Corporate Match
Greg Fiscus
Pamela L. Howard
Humana Foundation
Kroger Community Rewards
New Age Auto Parts
Michael & Lisbeth Vogel

Donors, $75 – $150
Anonymous
M. J. & A. M. Aman
Scott & Holly Brown
Clark County REMC
Jamie Cutrell
Nan Diederich
Forcht Bank "Hat Fundraiser"
Sandy Franklin
Michael A. Gatton
in honor of John G. Gatton
James & Tracey Gibson
Rex Howard
Ursela Kamala
Paul & Amy Kilgore
Lindsay Martin
Vivian Marcum
Ann Mancini
James & Sandra Richardt
in honor of Nancy Cutrell
Pete & Bev Slapikas
Scott's Performance Engine Center
Donna Steen

Donors, Up to $74
Benevity Community Impact Fund
William Bosserman
Nancy S. Dudley
G. Myers Trucking
Carol Hayes
Jennifer Hitt
Jessica Houchens
Timothy & Kimberly Lawton
Ruth Ann LeVay
in memory of Timothy LeVay
Cory & Whitney Meadows
Mark & Gretchen Muchnik
Lewis & Betty Owen
in honor of Zak Jarrett
Monica & Ronnie Poynter
Gary & Jana Scarbrough
John & Edie Shackelford
Leeta Williams
Women of Immanuel
Gail Yates
in honor of Kevin Loeser

Do The Five

Follow these steps to prevent or reduce complications of bleeding disorders

1. Get an annual comprehensive checkup at a hemophilia treatment center.
2. Get vaccinated – Hepatitis A and B are preventable.
3. Treat bleeds early and adequately.
4. Exercise to protect your joints.
5. Get tested regularly for blood-borne infections.

To find out more about the National Prevention Program developed by the National Hemophilia Foundation in collaboration with the Centers for Disease Control and Prevention (CDC), click on www.hemophilia.org or call toll-free 800-42-HANDI.

KHF neither recommends nor endorses the products in this publication and does not make recommendations concerning treatment regimen for individuals. KHF suggests that you consult your physician or treatment center before pursuing any course of treatment. This publication is for general information only.

Vegasville

Mark your calendar,
March 5, 2016,
Vegasville Event.
You won't want to miss it!

KOSAIR CHARITIES
Protecting the Most Precious Gift of All

WHAS CRUSADE FOR CHILDREN

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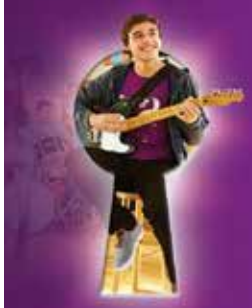

UNLOCKING YOUR SELF-POTENTIAL

ADVATE
[Antihemophilic Factor (Recombinant)]
There's more to life.

ADVATE SUPPORTS YOU BY IMPROVING YOUR PERSONAL INFUSION EXPERIENCE WITH THE BAXJECT III SYSTEM

The reconstitution process with the BAXJECT III system is easier, faster, and designed for you*

- An all-in-one, connected design[1]
- Broad selection of doses, providing opportunities for single-vial options[1]
- One-step activation with fewer steps for **faster** reconstitution—just press, swirl, flip and withdraw*[1,2]
- **Straightforward** pooling process if more than 1 vial is needed—no additional supplies required[1]

1/2 the time

Reconstitute ADVATE in about **half the time***[2]

*As compared with the BAXJECT II needleless transfer device.

Watch the ADVATE with BAXJECT III system reconstitution video and see how it all comes together at **ADVATE.com**

Share your experience using the ADVATE with BAXJECT III system at **www.BAXJECT3Survey.com**

ADVATE [Antihemophilic Factor (Recombinant)] Important Information

Indications

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 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

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.

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.
- Have been told that you have inhibitors to factor VIII (because ADVATE may not work for you).

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.

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, dizziness, hematoma, abdominal pain, hot flashes, swelling of legs, diarrhea, chills, runny nose/congestion, nausea/vomiting, sweating, and rash.

Tell your healthcare provider 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 following page for Brief Summary of ADVATE full Prescribing Information.

References: 1. ADVATE Prescribing Information. Westlake Village, CA: Baxter Healthcare Corporation; May 2015. **2.** Data on file.

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Baxalta

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
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 1-888-4-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.

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Antihemophilic factor (recombinant)

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ALPROLIX®
[Coagulation Factor IX (Recombinant), Fc Fusion Protein]

A treatment for hemophilia B

PROTECTION* FROM BLEEDS

Starting with at least a week between prophylaxis infusions

Dosing regimen can be adjusted based on individual response.

*Protection is the prevention of bleeding episodes using a prophylaxis regimen.

To learn more, contact CoRe Manager **Tricia Oppelt** at **tricia.oppelt@biogen.com** or call **585-737-9060**.

INDICATIONS AND IMPORTANT SAFETY INFORMATION

Indications

ALPROLIX, Coagulation Factor IX (Recombinant), Fc Fusion Protein, is a recombinant DNA derived, coagulation factor IX concentrate indicated in adults and children with hemophilia B for:

- Control and prevention of bleeding episodes
- Perioperative management
- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes

ALPROLIX is not indicated for induction of immune tolerance in patients with hemophilia B.

Important safety information

Do not use ALPROLIX if you are allergic to ALPROLIX or any of the other ingredients in ALPROLIX.

Tell your healthcare provider if you have or have had any medical problems, take any medicines, including prescription and non-prescription medicines, supplements, or herbal medicines, have any allergies and all your medical conditions, including if you are pregnant or planning to become pregnant, are breastfeeding, or have been told you have inhibitors (antibodies) to factor IX.

Allergic reactions may occur with ALPROLIX. Call your healthcare provider or get emergency treatment right away if you have any of the following symptoms: difficulty breathing, chest tightness, swelling of the face, rash, or hives.

Your body can also make antibodies called "inhibitors" against ALPROLIX, which may stop ALPROLIX from working properly.

ALPROLIX may increase the risk of formation of abnormal blood clots in your body, especially if you have risk factors for developing clots.

Common side effects of ALPROLIX include headache and abnormal sensation of the mouth. These are not all the possible side effects of ALPROLIX. Talk to your healthcare provider right away about any side effect that bothers you or does not go away, and if bleeding is not controlled using ALPROLIX.

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 Brief Summary of full Prescribing Information on the next page for additional safety information. This information is not intended to replace discussions with your healthcare provider.

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ALPROLIX [Coagulation Factor IX (Recombinant), Fc Fusion Protein], Lyophilized Powder for Solution For Intravenous Injection.

FDA Approved Patient Information

ALPROLIX™ /all' pro liks/ [Coagulation Factor IX (Recombinant), Fc Fusion Protein]

Please read this Patient Information carefully before using ALPROLIX™ and each time you get a refill, as there may be new information. This Patient Information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is ALPROLIX™?

ALPROLIX™ is an injectable medicine that is used to help control and prevent bleeding in people with hemophilia B. Hemophilia B is also called congenital Factor IX deficiency.

Your healthcare provider may give you ALPROLIX™ when you have surgery.

Who should not use ALPROLIX™?

You should not use ALPROLIX™ if you are allergic to ALPROLIX™ or any of the other ingredients in ALPROLIX™. Tell your healthcare provider if you have had an allergic reaction to any Factor IX product prior to using ALPROLIX™.

What should I tell my healthcare provider before using ALPROLIX™?

Tell your healthcare provider about all of the medicines you take, including all prescription and non prescription medicines, such as over-the-counter medicines, supplements, or herbal medicines.

Tell your doctor about all of your medical conditions, including if you:

- are pregnant or planning to become pregnant. It is not known if ALPROLIX™ may harm your unborn baby.
- are breastfeeding. It is not known if ALPROLIX™ passes into breast milk or if it can harm your baby.
- have been told that you have inhibitors to Factor IX (because ALPROLIX™ may not work for you).

How should I use ALPROLIX™?

ALPROLIX™ should be administered as ordered by your healthcare provider. You should be trained on how to do infusions by your healthcare provider. Many people with hemophilia B learn to infuse their ALPROLIX™ by themselves or with the help of a family member.

See the Instructions for Use for directions on infusing ALPROLIX™. The steps in the Instructions for Use are general guidelines for using ALPROLIX™. Always follow any specific instructions from your healthcare provider. If you are unsure of the procedure, please ask your healthcare provider.

Do not use ALPROLIX™ as a continuous intravenous infusion.

Contact your healthcare provider immediately if bleeding is not controlled after using ALPROLIX™.

What are the possible side effects of ALPROLIX™?

Common side effects of ALPROLIX™ include headache and abnormal sensation in the mouth.

Allergic reactions may occur. Call your healthcare provider or get emergency treatment right away if you have any of the following symptoms: hives, chest tightness, wheezing, difficulty breathing, or swelling of the face.

ALPROLIX™ may increase the risk of forming abnormal blood clots in your body, especially if you have risk factors for developing blood clots.

Your body can also make antibodies called, "inhibitors," against ALPROLIX™, which may stop ALPROLIX™ from working properly. Your healthcare provider may need to test your blood for inhibitors from time to time.

These are not all the possible side effects of ALPROLIX™. Talk to your healthcare provider about any side effect that bothers you or that does not go away.

How should I store ALPROLIX™?

Store ALPROLIX™ vials at 2°C to 8°C (36°F to 46°F). Do not freeze.

ALPROLIX™ vials may also be stored at room temperature up to 30°C (86°F) for a single 6 month period.

If you choose to store ALPROLIX™ at room temperature:

- Note on the carton the date on which the product was removed from refrigeration.
- Use the product before the end of this 6 month period or discard it. Do not return the product to the refrigerator.
- Do not use product or diluent after the expiration date printed on the carton, vial or syringe.

After Reconstitution:

- Use the reconstituted product as soon as possible; however, you may store the reconstituted product at room temperature up to 30°C (86°F) for up to 3 hours. Protect the reconstituted product from direct sunlight. Discard any product not used within 3 hours after reconstitution.
- Do not use ALPROLIX™ if the reconstituted solution is cloudy, contains particles or is not colorless.

What else should I know about ALPROLIX™?

Medicines are sometimes prescribed for purposes other than those listed here. Do not use ALPROLIX™ for a condition for which it was not prescribed. Do not share ALPROLIX™ with other people, even if they have the same symptoms that you have.

Manufactured by
Biogen Idec Inc.
14 Cambridge Center
Cambridge, MA 02142
U.S. License # 697

Alphanate®

Antihemophilic Factor/von Willebrand Factor Complex (Human)

Physician **Preferred**

ALPHANATE is the **preferred plasma-derived FVIII** product for the treatment of **hemophilia A** among hematologists practicing in HTCs.*

*Results are statistically significant with a 95% confidence interval with a 6.5% margin of error and are based on a blinded national survey of 75 HTC-based Hematologists from a list of federally and non-federally funded HTCs within the US, conducted and validated by a reputable, independent third party, Adivo Associates LLC, on behalf of Grifols USA from October 2014 - January 2015. In order to qualify to complete the survey, Hematologists were rigorously screened according to market research standards having the necessary experience in the relevant treatment segment. Respondents were asked to assume no difference in terms of availability, cost, and reimbursement when indicating their most preferred plasma-derived FVIII brand.

HTC=Hemophilia Treatment Center; pdFVIII=plasma-derived factor VIII

Learn more at **alphanate.com**

Indications

ALPHANATE® (antihemophilic factor/von Willebrand factor complex [human]) is indicated for:

- Control and prevention of bleeding in patients with hemophilia A
- Surgical and/or invasive procedures in adult and pediatric patients with von Willebrand disease (VWD) in whom desmopressin (DDAVP®) is either ineffective or contraindicated. It is not indicated for patients with severe VWD (Type 3) undergoing major surgery

Important Safety Information

ALPHANATE is contraindicated in patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components.

Anaphylaxis and severe hypersensitivity reactions are possible. Should symptoms occur, treatment with ALPHANATE should be discontinued, and emergency treatment should be sought.

Development of activity-neutralizing antibodies has been detected in patients receiving FVIII containing products. Development of alloantibodies to VWF in Type 3 von Willebrand disease (VWD) patients has been occasionally reported in the literature.

Thromboembolic events may be associated with AHF/VWF Complex (Human) in VWD patients, especially in the setting of known risk factors.

Intravascular hemolysis may be associated with infusion of massive doses of AHF/VWF Complex (Human).

Rapid administration of a FVIII concentrate may result in vasomotor reactions.

Plasma products carry a risk of transmitting infectious agents, such as viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent, despite steps designed to reduce this risk.

The most frequent adverse events reported with ALPHANATE in >5% of patients are respiratory distress, pruritus, rash, urticaria, face edema, paresthesia, pain, fever, chills, joint pain, and fatigue.

Please see brief summary of ALPHANATE full Prescribing Information on adjacent page.

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.

For more information: **Grifols Biologicals Inc.**
Tel. 888-GRIFOLS (888-474-3657)

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