Summer 2016

KHF Hemosphere

2016 Kentucky Hemophilia Walk

The Walk date is Saturday, October 8 at the same location as before, lovely Wetherby Park in Middletown. Walkers should register on line and donations should also be made on line when possible. Simply go to **walk.hemophilia.org/Louisville** to register and to make a donation.

An easy way to track your progress is to download the free Hemophilia Walk app on your smart phone.

The more money you raise via family, friends, co-workers, and others in your circle of personal and business contacts, the better the prizes are that you can win, and the more Kentucky's bleeding disorders community will benefit from your efforts. Everyone is invited to participate in the Walk.

Remember, as you sign up that the Hemophilia Walk is a powerful community from which we together grow a network to help us create change now and for the generations who will come after!

FVII Gene Therapy Trial in Dogs; New FIX and HCV Drugs FVII

FVII Gene Therapy Trial Update

Patients with factor VII (FVII) deficiency share your pain. Like hemophilia A and B, they experience joint and muscle bleeds, bruising and bleeding after surgery. Many babies are diagnosed after a life-threatening bleed in the gastrointestinal tract or brain during their first 6 months of life. There is an approved recombinant clotting factor they can use to treat bleeds, but it doesn't stay in the bloodstream long and is expensive.

A study published in the December 23, 2015, online issue of *Blood* showed that a gene therapy trial in dogs was successful, bringing hope for FVII patients. Researchers at the Children's Hospital of Philadelphia (CHOP) and the University of North Carolina at Chapel Hill injected one dose of a genetically engineered FVII gene into dogs using an adeno-associated virus (AAV). The AAV is the transport system to sneak the modified genes into the body in a way that the immune system won't recognize as foreign.

The dogs used in the study come from a colony at UNC-Chapel Hill. Not only did they have the FVII deficiency, but their mutation was the same as that in the majority of humans. The dogs maintained therapeutic levels of FVII, one for as long as three years. "Our data are the first to demonstrate feasibility, safety, and long-term duration of AAV gene therapy for factor VII deficiency," said Paris Margaritis, DPhil, lead investigator and hematology researcher at CHOP in a UNC-Chapel Hill press release. "The table is now set to propose clinical trials that would treat people who suffer from this disease."

New Drugs For You

Factor concentrates that last longer in the bloodstream may mean you can put more space between infusions. That's the goals for CSL Behring's Idelvion® for hemophilia B, or factor IX (FIX) deficiency. By linking the FIX protein to albumin, a blood protein, the factor product circulates longer. According to the company, it is the first and only coagulation FIX recombinant albumin fusion protein to treat hemophilia B.

In the PROLONG-9FP clinical trial 90 subjects ranging in age from 1 to 61 were tested. They all had FIX levels less than or equal to 2%. Those in the prophylaxis arm showed annualized bleeding rates of 0. Their FIX levels measured greater than 5%, transforming them from severe to mild hemophilia. Patients in the on-demand arm controlled 94% of bleeds with 1 infusion; 99% of bleeds required 1-2 infusions. The most prevalent side effect was headache.

Idelvion® is approved for prophylaxis, on-demand treatment and perioperative bleeding for children and adults. The manufacturer says that with this long-acting recombinant FIX therapy, some patients 12 and older may be able to stretch the time between infusions to up to 14 days.

In January 2016, a new oral hepatitis C virus (HCV) drug was approved by the FDA. Merck's Zepatier™ is for patients with chronic HCV infection, genotypes 1 and 4. It contains elbasvir, an NS5A replication complex inhibitor, and grazoprevir, an NS3/4A protease inhibitor. Some patients will take it with ribavirin.

The clinical trials for Zepatier™ were conducted for 12 or 16 weeks on 1,371 subjects. Some had failed previous trials, others had compensated cirrhosis and HIV-1 co-infection. Still others had severe kidney damage and were on dialysis. The drug was highly effective in providing sustained viral response (SVR), a "cure," 12 weeks after treatment ended. SVR rates were 94% to 97% for those with HCV-1 and 97% to 100% for HCV-4. Side effects included anemia, headache, fatigue and nausea. The label will warn about the possibility of elevated liver enzymes. Zepatier™ is not recommended for people with moderate to severe liver impairment.

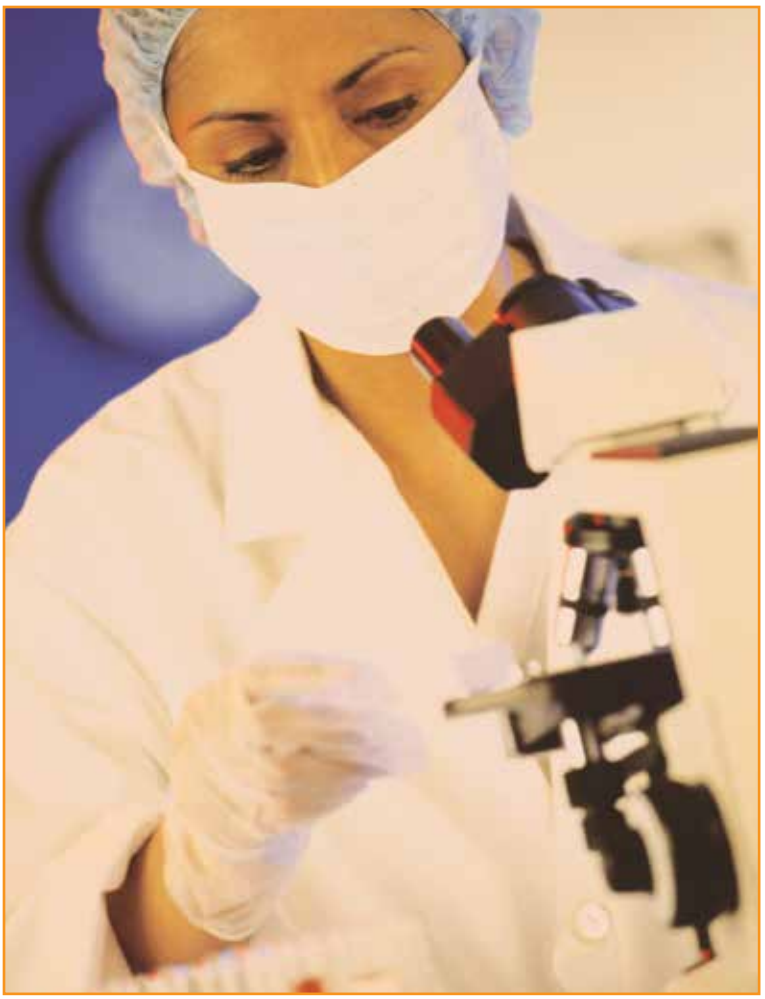
Source: *S*arah M. Aldridge, MS. " FVII Gene Therapy Trial in Dogs; New FIX and HCV Drugs." *HemAware,* Summer 2016, Volume 21, Issue 3.

SIPPET Study Results Published in *The New England Journal of Medicine*

The detailed findings of the much anticipated SIPPET (Survey of Inhibitors in Plasma-Products Exposed Toddlers) study were published today, May 26, 2016. The study, "A Randomized Trial of Factor VIII and Neutralizing Antibodies in Hemophilia A," appeared in *The New England Journal of Medicine*. The lead investigator was Flora Peyvandi, MD, University of Milan.

Peyvandi and fellow investigators found that previously-untreated patients (PUPs) had a significantly higher incidence of inhibitors when treated with recombinant factor VIII (rFVIII) than those treated with plasma-derived factor VIII (pdFVIII) containing von Willebrand factor (VWF). Developing an inhibitor to treatment remains the most prominent and challenging complication for clinicians, occurring in approximately 30% of hemophilia patients globally.

Back in December, a preview of the SIPPET findings presented during the American Society of Hematology's annual conference raised considerable interest among patients, providers and industry. While earlier studies have assessed the overall risk of inhibitor development in patients with hemophilia, the SIPPET study is the first large-scale international trial to randomize patients prospectively for the immunogenicity of pdFVIII vs. rFVIII usage.



SIPPET was a prospective randomized study which took place between January 2010 and December 2014 and collected data on 251 children (<6 years of age with severe hemophilia A) from 42 sites in 14 countries in Africa, North and South America, Asia and Europe. The authors reported that rFVIII was associated with an 87% higher incidence than pdFVIII. Half of the patients were randomly assigned to receive either pdFVIII or rFVIII. The authors reported an overall inhibitor incidence rate of 26.8%.

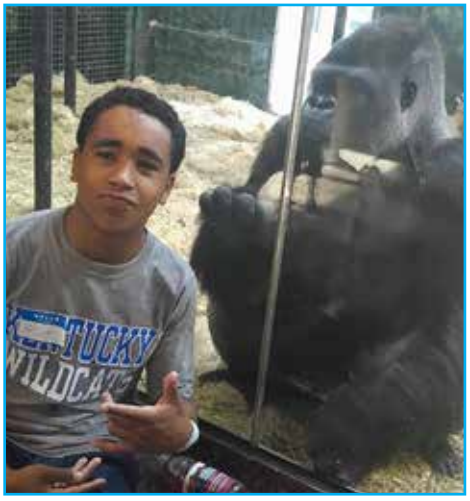
The National Hemophilia Foundation's Medical and Scientific Advisory Council (MASAC) will be reviewing the full study, making a thorough assessment of these findings and best determine what changes may be needed to the current MASAC recommendations for PUPS."

Source: *New England Journal of Medicine*, original article, published May 26, 2016

Event News

Family Day at the Louisville Zoo and Walk Call to Action

At the beginning of summer, the annual Family Day at the Louisville Zoo prompts many families from Kentucky's bleeding disorders community to travel to Louisville for a day of information, fellowship, and fun.



The children enjoy seeing a great variety of native and exotic animals and other attractions the Louisville Zoo has to offer as well as the carnival games and cool prizes we have waiting for them. Parents have an opportunity to meet other families, view exhibits by pharmaceutical and home care companies, and participate in the popular door prize drawing.

Our Call to Action for participation in this year's Kentucky Hemophilia Walk resulted in several enthusiastic commitments. This year's zoo event was funded in part by Accredo, Baxalta, Bayer HealthCare, Biogen, BioRx, CSL Behring, CVS Caremark, Matrix, Novo Nordisk, Octapharma, Option Care, and Pfizer.

Camp Discovery ~ KHF Summer Camp

KHF's summer camp for children and teens with bleeding disorders and their siblings commenced in mid-July for a five-day, overnight adventure. Camp was packed with recreational, educational, and cultural activities designed to entertain, teach, and motivate our campers. The goal is for campers to learn how to: manage their bleeding disorder, live healthy and productive lives, be physically active, interact with and befriend others, and have fun just like any other kid in a safe and supervised camp setting.

Event News

Our counselors and infirmary staff did a marvelous job in leading the way toward these goals, under the leadership of our Camp Director, Paula Bias; Assistant Camp Director, Justin Lindhorst; and Infirmary Director, Donna Haffler, RN. We appreciate the commitment of our camp volunteers to the success of our summer camp and to ensuring a positive experience for our campers and youths.

Thirty-seven youngsters and older teens who are transitioning into beginning counselor roles participated this year. Of special delight were ziplining across the lake, playing capture the flag, swimming every day, solving a Breakout Louisville mystery, a visit by Liberty Nature Center's raptors, final night Mexican dance party, and of course, learning how to stick yourself, which offers greater independence and freedom for managing a lifelong bleeding disorder.

Summer camp was supported by generous grants from Kosair Charities, the WHAS Crusade for Children and Baxalta and additional support from Accredo, Bayer HealthCare, CSL Behring, Grifols, and Pfizer.

Play A Round For A Cure

The "Play A Round For A Cure" Golf Scramble is one of KHF's primary fundraisers. This event takes place at Oxmoor Country Club's golf course in Louisville. Seventy-two players convene annually to enjoy eighteen holes of golf at this popular golf course. Of course, lunch, dinner, silent auction, and a variety of contests and prizes that we provide add to the appeal of this important fundraiser.

Team winners were in 1st place, CSL Behring; 2nd place, Pfizer; and 3rd place, Baxalta I. Seventeen year-old Noah Coy of Louisville won the putting contest for a second time, and Lindsay Chaput of Louisville won the $580 Ball Drop Raffle.

The event raised $18,000 for KHF's programs and services. We appreciate the companies who sponsored this fundraiser. They were Bayer HealthCare (Gold Sponsor); Baxalta, CSL Behring, Novo Nordisk, and Pfizer (Silver Sponsors); Octapharma, (Bronze Sponsor); Cottrill's Pharmacy, CVS Caremark, Paragon Health Care, Team Plus Sponsors; Accredo, BioRx, Robert H. Clarkson Insurance Group, Friends of Clear Creek, Kosair Charities, and Team Bonsai; Team and Player Sponsors.

More News

Kentucky Hemophilia Foundation Donors

Thank You To All Donors For Their Generous Contributions

April 1, 2016 – June 30, 2016

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KHF Membership July 1, 2015 - June 30, 2016

We appreciate your involvement and support!

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In Memory

January 1 – June 30, 2016

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

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William L. Farmer, Sr.
Mrs. William L. Farmer, Sr.
Albert George Loeser, Sr.
KW Container
Bonnie J. Seaton
Gail F. Yates for Scholarship Fund
Regina Loeser
KW Container
Jim Pierce
Gail F. Yates for Scholarship Fund

Upcoming KHF Events

Helping Hats Fundraiser

October/November 2016

Poinsettia Sale Fundraiser

November/December 2016

Holiday Year-End Family Event

Sunday, December 11, 2016
American Legion Highland Post
Louisville, KY

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.

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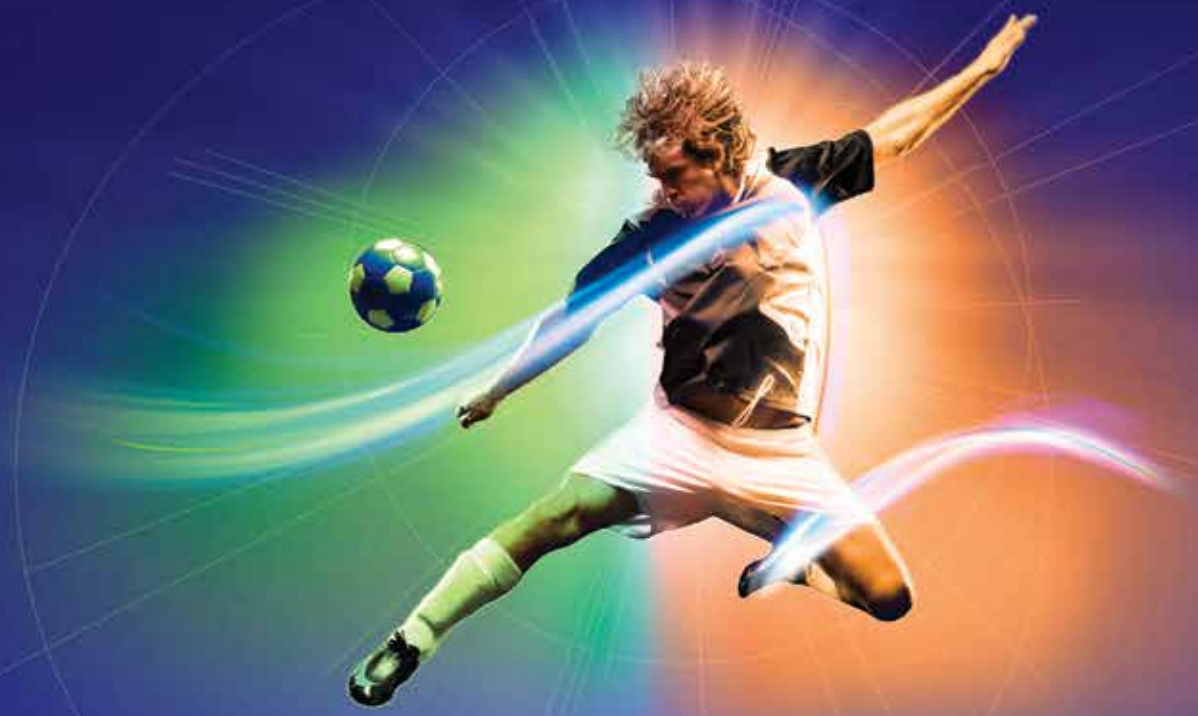

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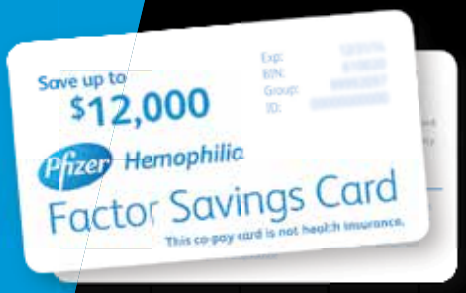
IDELVION®
Coagulation Factor IX (Recombinant), Albumin Fusion Protein

Pfizer Hemophilia

Save up to $12,000 in 2016!

Eligible patients can save up to $12,000 annually on co-pay, deductible, and coinsurance costs with the Pfizer Factor Savings Card.



Beginning in 2016 (follow these steps):

1. Get your prescription for a Pfizer factor product from your doctor.
2. Visit **PfizerFactorSavingsCard.com** and fill out a brief registration form.†
3. Save and print your card right from your computer. The card is now activated.
4. Keep your card and use it for every purchase until the maximum benefit has been reached or the card has expired, whichever comes first.

Get your card online now…

Scan the QR code or visit **PfizerFactorSavingsCard.com** to download your card today.*

This card will be accepted only at participating pharmacies. This card is not health insurance. No membership fees. You will receive a total benefit of $12,000 per calendar year, or the amount of your co-pay over one year, less a patient financial responsibility of $10 per month, whichever is less.

If you have any questions about the use of the Pfizer Factor Savings Card, please call 1-888-240-9040 or send questions to: Pfizer Factor Savings Program, 6501 Weston Parkway, Suite 370, Cary, NC 27513. The Pfizer Factor Savings Card cannot be combined with other offers and is limited to one per person.

*Terms and conditions apply; visit PfizerFactorSavingsCard.com for complete terms and conditions. For commercially insured only. Medicare/Medicaid beneficiaries are not eligible.

†You can also request a card from your doctor, or by calling 1-855-PFZ-HEMO.

Pfizer

Your IXINITY® Product Specialist, Brent Smith

"I enjoy partnering with families to help connect them with the best treatment options that will truly help improve their overall quality of life."

Let's talk about IXINITY and how you can get the most out of Emergent-sponsored programs, including the **Generation IX Project** and the **B More™ Scholarship Program.**

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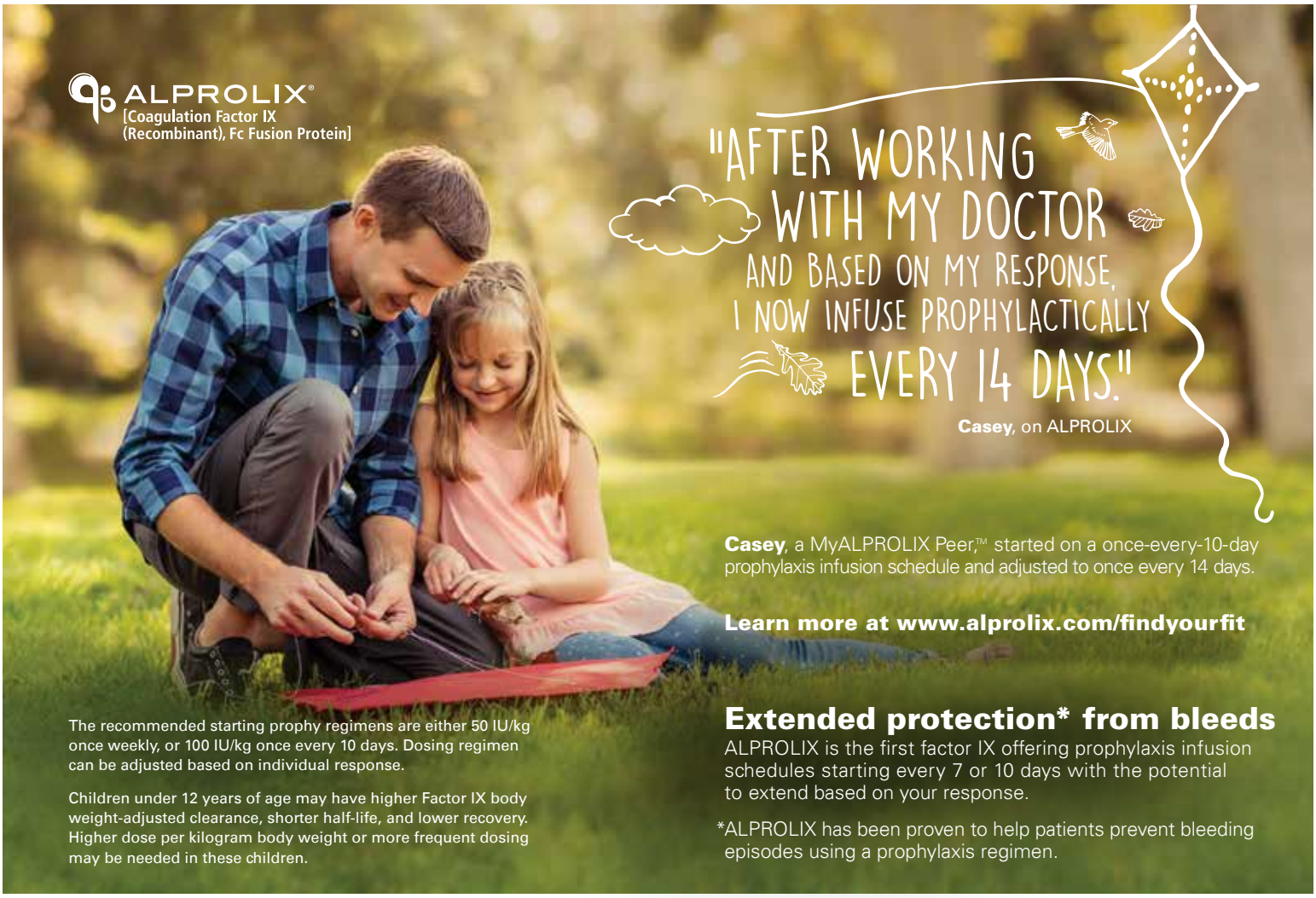

Indications and Important Safety Information

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:

- On-demand treatment and control of bleeding episodes
- Perioperative management of bleeding
- Routine prophylaxis to 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. This information is not intended to replace discussions with your healthcare provider.

Biogen

FIX-US-0573 V2 03/2016

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.

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Alphanate®
antihemophilic factor/von Willebrand factor complex (human)

PREFERRED BY PHYSICIANS

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

Indications

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

- Control and prevention of bleeding episodes and perioperative management in adult and pediatric patients with factor VIII (FVIII) deficiency due to 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 with ALPHANATE. Discontinue use of ALPHANATE if hypersensitivity symptoms occur, and initiate appropriate treatment.

Development of procoagulant activity-neutralizing antibodies (inhibitors) has been detected in patients receiving FVIII-containing products. Carefully monitor patients treated with AHF products for the development of FVIII inhibitors by appropriate clinical observations and laboratory tests.

Thromboembolic events have been reported with AHF/VWF complex (human) in VWD patients, especially in the setting of known risk factors.

Intravascular hemolysis may occur with infusion of large doses of AHF/VWF complex (human).

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

Because ALPHANATE is made from human plasma, it may carry a risk of transmitting infectious agents, eg, viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent, despite steps designed to reduce this risk.

Monitor for development of FVIII and VWF inhibitors. Perform appropriate assays to determine if FVIII and/or VWF inhibitor(s) are present if bleeding is not controlled with expected dose of ALPHANATE.

The most frequent adverse drug reactions reported with ALPHANATE in >1% of infusions were pruritus, headache, back pain, paresthesia, respiratory distress, facial edema, pain, rash, and chills.

Please see accompanying full Prescribing Information for ALPHANATE in pocket for complete prescribing details.

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.

Learn more at
alphanate.com

BAYER
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Free Trial Program*

- Enroll today for up to 6 free doses†
- Delivered to your home free of charge

Access to Therapy

We might be able to provide treatment at no cost if you‡:

- Experience challenges getting insurance coverage for a Bayer product
- Are uninsured or underinsured
- Are between jobs and are experiencing a gap in insurance coverage

$0 Co-pay Program§

If you have private insurance, you may be eligible for the $0 Co-pay Program.

- You may be able to receive up to **$12,000 in assistance** per year, regardless of income
- **Assistance is awarded per patient.** Multiple members of the same household can apply
- Enrollment can be completed in **one short phone call**

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- Consult with an expert in insurance
- Spanish-speaking Case Specialists are also available

CALL

1-800-288-8374

8:00 AM-8:00 PM (ET) Monday-Friday. Spanish-speaking Case Specialists are also available.

*The Free Trial Program is available to newly diagnosed patients and patients who are currently using other therapy. Participation in the Free Trial Program is limited to 1 time only. This program is complimentary and is not an obligation to purchase or use a Bayer product in the future. Reselling or billing any third party for the free product is prohibited by law.

†The Free Trial Program includes up to 6 free doses to a maximum of 5,000 IU for new patients and 40,000 IU for previously treated patients.

‡The program does not guarantee that patients will be successful in obtaining reimbursement. Support medication provided through Bayer's assistance programs is complimentary and is not contingent on future product purchases. Reselling or billing any third party for free product provided by Bayer's patient assistance programs is prohibited by law. Bayer reserves the right to determine eligibility, monitor participation, determine equitable distribution of product, and modify or discontinue the program at any time.

§People with private, commercial health insurance may receive co-pay or co-insurance assistance based on eligibility requirements. The program is on a first-come, first-served basis. Financial support is available for up to 12 months. Eligible patients can re-enroll for additional 12-month courses. The program is not for patients receiving prescription reimbursement under any federal-, state-, or government-funded insurance programs, or where prohibited by law. All people who meet these criteria are encouraged to apply. Bayer reserves the right to discontinue the program at any time.

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