Winter 2016/Spring 2017

KHF Hemosphere

We're More Than Carriers

Laurie Kelley

Not even 10 years ago, you might have been told that women could get hemophilia, but that it was very rare. And that probably, only about 10 women with hemophilia[1] existed in the US. Today, those statements are totally wrong. Why?

Why is the relatively small number of women as "bleeders" about to shift into the thousands and upend all our statistics? Because the belief that only males get hemophilia is no longer valid. Hemophilia has been described as mostly affecting males because the gene for hemophilia was found on the X chromosome. You probably know how it goes: men have only one X chromosome and can inherit the disorder from a mother who also has an affected X chromosome; women "carry" the disorder and pass it to their offspring. So traditionally, a woman who was dubbed a carrier might have low levels of factor, and if she showed some abnormal bleeding, she was delicately called a "symptomatic carrier." But she was most definitely not called a person with hemophilia. Not until now.

Where does that leave YOU, a symptomatic carrier—a woman with an affected X chromosome, who has low factor levels and who bleeds? You're pretty much a woman without a treatment plan, and that can be dangerous. Today, women with low factor levels who carry the hemophilia gene are calling themselves "women with hemophilia." And they're also calling for big changes: in our community's beliefs, and in how women are treated by hemophilia treatment centers (HTCs).

Silent Suffering

So many women who are labeled symptomatic carriers have suffered deeply, lacking a proper hemophilia diagnosis and appropriate treatment. "Do I consider myself a woman with a bleeding disorder?" asks Rita Epstein, mother of an adult with hemophilia. "You bet I do! During various surgical procedures over the years, I had major bleeding problems that actually caused doctors to stop the surgery. Once I was identified and pretreated as well as post-treated as a person with hemophilia, the surgical field was clear [of blood] and my procedures were easily handled."

Mary Boudreaux notes, "I've had more [bleeding] issues than my brother who has hemophilia! I've never been diagnosed with hemophilia—only as a carrier—and most doctors I see don't even want to hear about hemophilia because they say only males have that."

"I look back and think how different some of my experiences could have been, had I known I had a bleeding disorder," reflects Stormy Woods Johnson. "I could have avoided 45-day periods, a blood transfusion, and possibly four miscarriages. My ankle has given me trouble for over 15 years. It stayed swollen and painful for over three… *continued on the next page*

See more Holiday Party photos inside

We're More Than Carriers

cont...

years before I finally found out I had tears in the tendon and large amounts of blood in it."

With a correct hemophilia diagnosis, so much suffering could have been avoided. But through the years, most of the US medical community grew comfortable assigning the label "symptomatic carrier" to women with signs and symptoms of bleeds who had children with hemophilia. The focus was almost always on the boys with hemophilia.

Treatment Jeopardized

Being labeled only a carrier can result in a more casual medical approach to treatment, whether for surgery, childbirth, menses, or just regular activities. Melissa Howell admits that most doctors say to her, "Oh, you're a carrier, so we don't need to do anything else."

By using the carrier label, physicians may even encourage women with bleeding issues to ignore their instinct that something is wrong. Brandi Worthington recalls, "I always thought I had anemia, and didn't know what was wrong because I bruised easily and had very heavy periods twice a month. When I got into a car accident while pregnant with my first child, I had unbearable pain. My doctor said it was just normal pregnancy pain."

Brandi ended up with internal bleeding and a huge blood clot that became infected. Her nephew had hemophilia, but no one realized she might be a carrier or have low factor levels. Five years after the accident and one month before the birth of her third child, who was diagnosed with hemophilia, Brandi tested positive as a carrier with mild hemophilia. "It was my nephew's nurse," she explains, "who said I should get my levels retested since I was pregnant again."

Audrey La Bolle shares, "When I was tested, I had less factor VIII than my son with hemophilia, but I was told by the hematologist at the HTC that a diagnosis of hemophilia could only be applied to males. I was 'just' a symptomatic carrier, even though I almost bled to death several times after surgeries and giving birth."

"I am a woman. I am a hemophilia carrier. I have bleeding issues," writes Michelle Thompson in her blog.[2] "They are not severe, usually, but I still have them. When I go to the dentist, when I strenuously exercise, when I bump something pretty hard, and when I clumsily fall. The bruises and bleeds come and I can feel them. But that isn't good enough for my HTC. I guess they want me to look like [I have severe hemophilia], swelling like a balloon to acknowledge that I am a woman and I bleed too. But my son is moderate/mild…When he has a bleed we treat it."

Sometimes it's difficult for the HTC to accurately diagnose; stress and hormones can affect factor levels. "You know what frustrates me the most?" seethes Tela Kirk-Aguilar. "It's when you are a 'symptomatic carrier,' and get tested to see if you might have hemophilia, but your levels are too high! The HTC thinks you're fine, but you get bruising and heavy periods; or you throw your knee out while your eight-year-old tells you, 'It sounds like a bleed, Mommy.' You can't do anything about it because you can't get factor!"

Even When You Are Diagnosed

It's an uphill battle to get correctly diagnosed and treated, because it's hard to change widespread beliefs in the medical community. Even women who are diagnosed sometimes aren't believed by the general medical community, or by payers.

Stormy was diagnosed with hemophilia just 18 months ago. Though she received the correct diagnosis, "I still feel I am treated differently than a male with hemophilia."

Mary Haugen insists, "The diagnosis of being a female with hemophilia is essential to our treatment. It opens doors for our insurance to cover treatment, better treatment by medical professionals, and a better life."

Genny Moore, mother of a child with hemophilia, says, "The HTC should understand the importance of properly identifying hemophilia. If the factor levels show mild, moderate, or severe range, it is important that we are identified as indeed having a bleeding disorder in order to ensure proper treatment especially in an accident or surgery."

We're More Than Carriers

cont...

But Stormy warns, "It will take time for the HTCs to really embrace the fact that we have hemophilia. I think some have accepted it openly, some have accepted it with caution, and some will never truly accept it. It will take a bit of time for them to treat us by symptoms and not gender or numbers."

Appropriate treatment can change women's lives. "The two weeks of factor replacement after my last delivery made my recovery amazing," recalls Michelle. "I'm not only talking about the amount of bleeding (that was so much less too!) but also the time it took to heal from the episiotomy and to just heal in general. Wow. If I'd known before that it could be like that, maybe we wouldn't have waited 10 years before having our last child."

Women with Hemophilia—Unite!

Mentioning the subject of women having hemophilia—or "women as bleeders," as Facebook friends often call themselves—creates a flood of opinions, from men and women. Women are frustrated. Men are supportive.

"Hemophilia symptomatic carriers—are you out there?" posts Michelle. "Let's start talking among ourselves and compare stories. If research studies could be done, then there would be information out there for the doctors to finally realize that their textbook answers will not cut it when it comes to women [with hemophilia]."

What are next steps? What can you do?

1. Get your factor levels correctly diagnosed at your HTC, and discuss your bleeding history.[3] Don't do this at your son's annual clinic visit, where the focus is on him. Make your own appointment. Remember, this is about YOU.
2. If your levels are 50% or lower, ask to be diagnosed as a person with hemophilia, not as a carrier or symptomatic carrier. Even women with factor levels of 60% can have bleeding problems.
3. Develop a treatment plan before dental procedures, childbirth, injuries, and surgeries. You might need a prescription for factor.
4. Invest in medical identification jewelry, just as you did for your child with hemophilia.
5. Get support from the community. Start with your local hemophilia organization—what are its opinions and policies about women being diagnosed with hemophilia? Make this a topic at your annual meeting.

We must also advocate for widespread changes in how we think about carriers and hemophilia. A carrier should never automatically be thought of as someone who has the gene for hemophilia but does not have the disorder. Women who are carriers and have low factor levels often have bleeding issues: bruising, bleeding into joints and muscles, and menstrual periods with abnormally heavy or prolonged bleeding. The moment a woman is diagnosed as a carrier, HTCs need to start investigating a hemophilia diagnosis and have a treatment plan in place.

Women who are defined as symptomatic carriers want the label removed permanently. They want to be known simply as "women with hemophilia" if their levels are lower than 50% and if they experience abnormal bleeding. If this change happens, women will have their own personalized treatment plans and access to factor concentrate.

This is what personalized healthcare is all about: identifying your unique medical and treatment needs, and addressing them, without limiting labels. If you're classified as a symptomatic carrier and believe you're not getting the personalized healthcare you need, call your HTC today and get the ball rolling.

1. Only women with severe hemophilia were considered to have hemophilia.
2. Michelle Thompson, "Hemophilia Symptomatic Carriers…Are You Out There?" chellebellebooks.blogspot.com, Feb. 29, 2012 (Accessed Sept. 1, 2016).
3. Labs at HTCs have more expertise in accurately measuring factor levels. Also, several tests should be performed at different visits because factor VIII levels can vary widely in response to stress and hormones. For example, stress causes an increase in factor VIII levels.

Event News

Year End Holiday Event

Nearly two hundred guests enjoyed themselves at our annual holiday celebration at the Clifton Center in Louisville. One could hear and feel the seasonal excitement that filled the room. Chef John Taylor provided us with a delicious assortment of hors d'oevres. This event's popular Bake Contest resulted in many delectable baked goods to be shared once the judging was completed. Contest winners were Leslie Houvenagle in 1st place with her "Nutty Putty Dump Cake;" Pat Tharp in 2nd place with her "Best Strawberry Cake Ever;" Myra Loeser in third place with her "Orange Liqueur Cake;" and David Houvenagle in 4th place with his "Choco Flan." Prizes awarded to these successful bakers were a Ninja blender, pressure cooker, beverage dispenser, and slow cooker. The silent auction featured many attractive items that our guests had brought to auction off. We thank them for their donations! Connie Thacker of Christian Fellowship entertained the little ones, while the adults mixed and mingled with old and new friends. Once the clock had moved past 4 p.m., the eyes of sixty expectant boys and girls were glued, so to speak, to the door wondering if Santa would pay them a visit. And yes, Santa arrived bearing gifts for all the children who had come to the event. Many a smile could be detected! Rounding out the event were door prizes for the adults and the uplifting feeling of having successfully rung in the Holiday Season! We thank all volunteers and sponsors who helped make this event possible! Sponsors were Accredo, Bayer HealthCare, Bioverativ, CSL Behring, CVS Caremark, First Choice, Grifols, NCHS, Shire.

Poinsettia Fundraiser

Thanks to the efforts of a dedicated group of volunteers, we were able to sell more than 2,400 plants during our annual Poinsettia Sale, KHF's longest running fundraiser. As reported in recent years, the competition with many retail outlets and other nonprofit entities increases every year. Our volunteers generated orders for almost half of this year's sales total, which is a wonderful and much appreciated accomplishment. The top orders came from Janet Goff & Sharon McMahan in Owensboro, Marion Forcht in Corbin, Sadalia Sturgill in Lebanon Junction, Tina Pelly in Campbellsville, Deborah and Glen Hitt, Sr. in Shelbyville, as well as the extended Meadors family, Jenifer Schultz, and Eric Marcum in Louisville. Many thanks to all volunteers who helped with this fundraiser.

Advocacy Day

KHF's 4th Annual Advocacy Day went very well by all accounts and achieved desired results. On February 28, a group of thirty peer advocates and supporters gathered for an early morning orientation and training session at the Capitol Annex in Frankfort, KY. Teams were formed to meet with various legislators to educate them about bleeding disorders and related issues and to express healthcare and insurance needs and concerns. The morning culminated with the presentation by Lieutenant Governor Hampton of a Proclamation issued by Governor Bevin in support of the month of March as Bleeding Disorders Awareness month. This was a wonderful tribute to our bleeding disorders community in Kentucky and a testimony to the awareness raising and change promoting power of peer advocacy.

KHF is very honored to be in receipt of this Proclamation. Coincidentally, it was a very poignant moment as NORD, the National Organization for Rare Disorders and KHF, Kentucky Hemophilia Foundation, were presented with their respective Proclamations side by side in the Capitol Rotunda as hemophilia is considered a rare disorder. A delicious wrap-up lunch at Serafini Restaurant concluded a successful Advocacy Day. Our thanks go to the planning committee, PSI, NHF, and the Tri-State Bleeding Disorder Foundation for their support and assistance. Funding was provided by Aptevo, Bayer HealthCare, Bioverativ, CSL Behring, Novo Nordisk, Pfizer, and Shire.

Event News

Vegasville

The 20th anniversary of our annual gala, proved to be the most successful ever. The event was started in 1998 as a fundraiser with a Mardi Gras theme by Clark and Sally Rhea. It was a wonderful event with all the trimmings of its central theme and immediately successful. As time went on, we added casino style gaming thanks to John Silletto and his friends, and eventually switched to a Vegas focus. This year, we added a 50/50 raffle to our gaming activities of Blackjack, various poker games, roulette, a dice game, and the grand prize drawing. Eric Marcum won the stunning emerald and diamond necklace, which was donated by Glen and Deborah Hitt. John Haas, who won the 50/50 raffle, graciously donated his win of $725 back to KHF.

Steve Fazzini entertained with Vegas classics during the cocktail hour and dinner period, while The Remedy, a fantastic local band, provided after dinner dance music that motivated many of our guests to hit the dance floor. Not only are they a great group of musicians, but they also perform pro bono for local charities. Our silent auction featured many sought after items including top notch must have's such as a week-long time share at a domestic or international resort of the winner's choosing, a Churchill Downs suite with food for sixteen for a day at the races, and an expertly prepared Italian dinner for six people cooked and in the successful bidder's home.

Thanks to a very generous matching donation by one of our primary supporters, the Special Appeal resulted in the largest amount donated at any of our Vegasville events preceded by a heartwarming testimonial about raising a child with a bleeding disorder. The testimonial was presented by Bradley Woods and his children Jackson and Izzi and centered on the family's daily living challenges, their involvement in KHF activities, and witnessing their children's excitement and personal growth through their participation in KHF's summer camp program. We thank our planning committee, headed by Melissa Hitt, all day of event volunteers, and the many generous donors and supporters who ensured the unparalleled success of this year's Vegasville fundraiser. Primary table sponsors were Forcht Bank, Shire, CSL Behring, Pfizer, Bayer HealthCare, Bioverativ, Kosair Charities, Novo Nordisk, Republic Bank, Amerimed, and Mr. & Mrs. Henry W. Boyd, III. The event raised over $70,000. Proceeds from the event help fund KHF's programs and services.

Washington Days

Eric and Venus Marcum and Sara Ceresa, all of Louisville, represented KHF this year at Washington Days. Because of their participation in KHF's annual Advocacy Day, they are well versed in advocating for the bleeding disorders community on a national level. Because of these peer advocacy efforts by representatives from all over the country, Washington legislators are quite familiar with the daily living challenges that the bleeding disorders community faces and their healthcare and insurance needs and fears. There is strength in number as it is said. More than five hundred peer advocates had their voices heard in Washington, DC, for legislators to take note of their concerns. We thank our advocates as well as all the others for their commendable efforts.

More News

KHF Membership
July 1, 2016 — June 30, 2017

Members, $20
James P. Huff
Ronald L. Swearingen

Supporting Members, $35
Susan Geralds
Judy Hayes
in memory of Jason Hayes
Mary E. Marasa
Donald L. Mattingly

Patron Members, $50
Sara Ceresa
Dr. David & Leslie Houvenagle
The Incorvia Family
Carol & John Nord
Stacey Powell & Family
Lonnie Surratt

Sustaining Members, $100
John & Leah Graham
Barbara W. Grayson
D. Spalding Grayson
Arthur Hackman
Fred & Darline Hartman
Thomas & Alice Hendrix
Vivian Marcum
Keith Peterson
Gail Yates
Cal & Nita Wayne Zehnder

Benefactor Members, $250
Deborah & Glen Hitt, Sr.
John & Pat Tharp

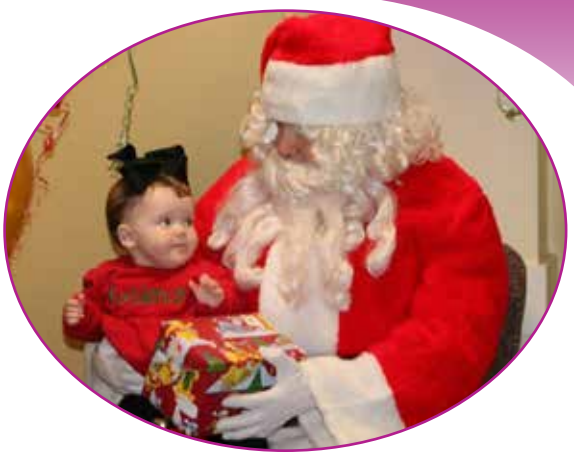
Champion/Corporate Members, $500
Ted & Jennifer Forcht
Terry & Marion Forcht
National Cornerstone Healthcare Service, Inc. (NCHS)
Kristen & Keith Urbahn and Benjamin and William

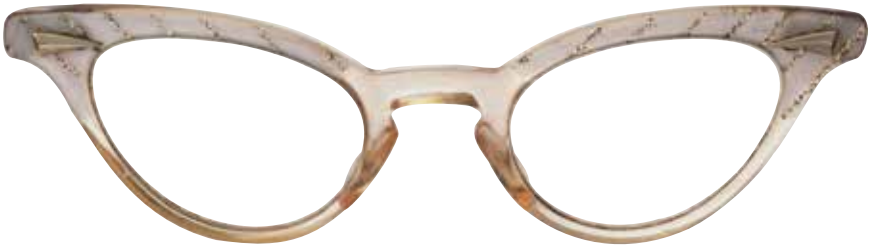
KHF awarded two $500 post-secondary education scholarships for the 2017 spring semester

The Herb Schlaughenhoupt, Jr. Memorial Scholarship was awarded to Emily Cieslak. Emily is the daughter of Dr. Joseph Cieslak and Cathy Cain. Emily attends the University of South Carolina in Columbia, South Carolina, where she majors in Biology. With a GPA of 3.427, she is a member of the University of South Carolina Honors College and will graduate this May with a Bachelor of Science degree in Biology.

The Betty Meadors Mattingly Memorial Scholarship was awarded to Andrew Harmon. Andrew is the son of Keith and Sharen Harmon and lives in Bedford, Kentucky. Andrew attends Jefferson Community Technical College of Carrollton, where he majors in Elementary Education. Andrew maintains a 3.5 GPA and expects to graduate in May 2019 with a Bachelor's degree.

More News





LOOKING AHEAD

Family Day at the Louisville Zoo – May 20

28th Annual "Play A Round For A Cure" Golf Scramble – June 26

Camp Discovery – July 16-20

Summer Family Event/Annual Education Meeting – August 19

4th Annual Kentucky Hemophilia Walk – October 14

Year End Holiday Event – December 3

In Memory

November 1, 2016 – March 31, 2017

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

Herman Barr
Dave Guethlein

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

Tom Graham
Agri-Sales Associates, Inc.
Jaimie Anglin
Clarion Class of Clearview Baptist Church in honor of our good friend and his family: Carl & Betty Bussey, Dee Crawford, Ellen Ingram, Al & Doris Parks, Gwen Shockley, Chris Tompkins, Ed & Catherine Thiele
Clearview Baptist Church
Buddy & Denise Hardison
Hardison, Englert, Rader & Co., P.C.
Myra S. Meetze
Larry Miller
Robert K. Miller & Alma L. Stevenson
Mike & Glenda Mitchell
Susan G. Neff
Lisa Scully
Peggy & Andrew Shawls
Terrence & Michele Smith
Edward & Catherine Thiele
Watkins/Gaunce Families
Pat & Frank Zeber

Alan Taylor Hall
Walter & Norma Hall

Al Loeser
Janet & Bruce Masterson

Regina Loeser
Janet & Bruce Masterson

Evelyn Sue Pitt
Joseph & Norma Davenport
John & Helen Haury
Gary & Gloria Wachtel

Herb Schlaughenhoupt, Jr.
Janet & Bruce Masterson

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.

Save the Date

10/14/17

Walk2 cure hemophilia KHF

To sign up for the Walk, go to:
hemophiliawalk.donordrive.com/event/KY

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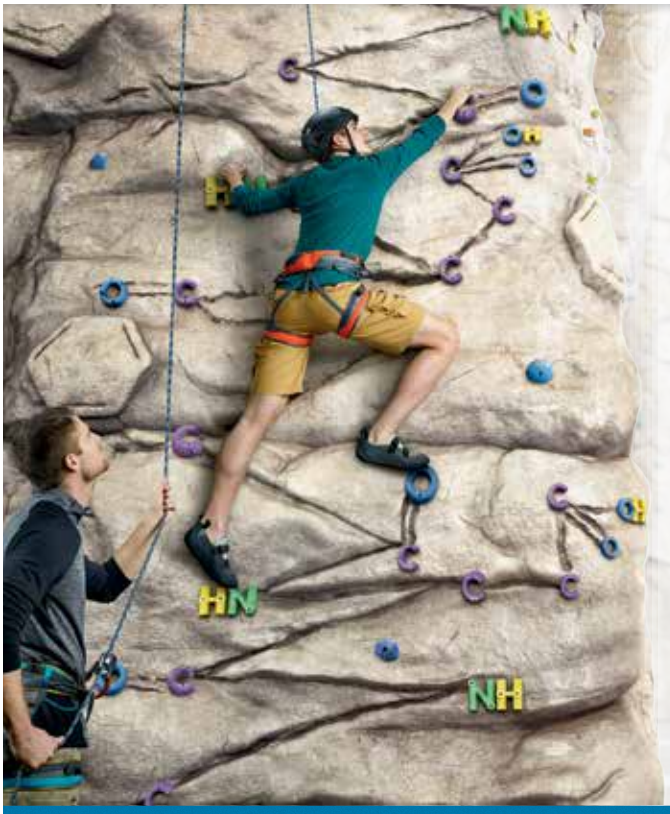


For adults and children with hemophilia A

REACH HIGHER

With the Long-lasting Protection of AFSTYLA

2x WEEKLY AVAILABLE

FDA-approved for dosing 2 or 3 times a week

ZERO BLEEDS (median AsBR*)

In clinical trials, whether dosed 2 or 3 times a week

COMPARABLE TO **NATURAL FACTOR VIII**

Identical to natural Factor VIII once activated

Zero inhibitors observed—Low incidence of side effects in clinical trials

In clinical trials, dizziness and allergic reactions were the most common side effects.

Visit AFSTYLA.com to sign up for the latest news

*Annualized spontaneous bleeding rate in clinical trials (interquartile range [IQR]=0–2.4 for patients ≥12 years; 0–2.2 for patients <12 years).

Important Safety Information

AFSTYLA is used to treat and control bleeding episodes in people with hemophilia A. Used regularly (prophylaxis), AFSTYLA can reduce the number of bleeding episodes and the risk of joint damage due to bleeding. Your doctor might also give you AFSTYLA before surgical procedures.

AFSTYLA is administered by intravenous injection into the bloodstream, and can be self-administered or administered by a caregiver. Your healthcare provider or hemophilia treatment center will instruct you on how to do an infusion. Carefully follow prescriber instructions regarding dose and infusion schedule, which are based on your weight and the severity of your condition.

Do not use AFSTYLA if you know you are allergic to any of its ingredients, or to hamster proteins. Tell your healthcare provider if you previously had an allergic reaction to any product containing Factor VIII (FVIII), or have been told you have inhibitors to FVIII, as AFSTYLA might not work for you. Inform your healthcare provider of all medical conditions and problems you have, as well as all medications you are taking.

Immediately stop treatment and contact your healthcare provider if you see signs of an allergic reaction, including a rash or hives, itching, tightness of chest or throat, difficulty breathing, lightheadedness, dizziness, nausea, or a decrease in blood pressure.

Your body can make antibodies, called inhibitors, against FVIII, which could stop AFSTYLA from working properly. You might need to be tested for inhibitors from time to time. Contact your healthcare provider if bleeding does not stop after taking AFSTYLA.

In clinical trials, dizziness and allergic reactions were the most common side effects. However, these are not the only side effects possible. Tell your healthcare provider about any side effect that bothers you or does 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 the following brief summary of full prescribing information on the adjacent page, and the full prescribing information, including patient product information, at AFSTYLA.com.

AFSTYLA® Antihemophilic Factor (Recombinant), Single Chain

AFSTYLA®, Antihemophilic Factor (Recombinant), Single Chain
For Intravenous Injection, Powder and Solvent for Injection
Initial U.S. Approval: 2016

BRIEF SUMMARY OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use AFSTYLA safely and effectively. See full prescribing information for AFSTYLA.

----------INDICATIONS AND USAGE----------
AFSTYLA®, Antihemophilic Factor (Recombinant), Single Chain, is a recombinant, antihemophilic factor indicated in adults and children with hemophilia A (congenital Factor VIII deficiency) for:

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

Limitation of Use
AFSTYLA is not indicated for the treatment of von Willebrand disease.

----------DOSAGE AND ADMINISTRATION----------
For intravenous use after reconstitution only.

- Each vial of AFSTYLA is labeled with the amount of recombinant Factor VIII in international units (IU or unit). One unit per kilogram body weight will raise the Factor VIII level by 2 IU/dL.
- Plasma Factor VIII levels can be monitored using either a chromogenic assay or a one-stage clotting assay – routinely used in US clinical laboratories. **If the one-stage clotting assay is used, multiply the result by a conversion factor of 2 to determine the patient's Factor VIII activity level.**

Calculating Required Dose:

Dose (IU) = Body Weight (kg) x Desired Factor VIII Rise (IU/dL or % of normal) x 0.5 (IU/kg per IU/dL)

Routine Prophylaxis:

- Adults and adolescents (≥12 years): The recommended starting regimen is 20 to 50 IU per kg of AFSTYLA administered 2 to 3 times weekly.
- Children (<12 years): The recommended starting regimen is 30 to 50 IU per kg of AFSTYLA administered 2 to 3 times weekly. More frequent or higher doses may be required in children <12 years of age to account for the higher clearance in this age group.
- The regimen may be adjusted based on patient response.

Perioperative Management:

- Ensure the appropriate Factor VIII activity level is achieved and maintained.

----------DOSAGE FORMS AND STRENGTHS----------
AFSTYLA is available as a white or slightly yellow lyophilized powder supplied in single-use vials containing nominally 250, 500, 1000, 2000, or 3000 International Units (IU).

----------CONTRAINDICATIONS----------
Do not use in patients who have had life-threatening hypersensitivity reactions, including anaphylaxis to AFSTYLA or its excipients, or hamster proteins.

----------WARNINGS AND PRECAUTIONS----------

- Hypersensitivity reactions, including anaphylaxis, are possible. Should symptoms occur, immediately discontinue AFSTYLA and administer appropriate treatment. (5.1)
- Development of Factor VIII neutralizing antibodies (inhibitors) can occur. If expected plasma Factor VIII activity levels are not attained, or if bleeding is not controlled with an appropriate dose, perform an assay that measures Factor VIII inhibitor concentration.
- If the one-stage clotting assay is used, multiply the result by a conversion factor of 2 to determine the patient's Factor VIII activity level.

----------ADVERSE REACTIONS----------
The most common adverse reactions reported in clinical trials (>0.5% of subjects) were dizziness and hypersensitivity.

To report SUSPECTED ADVERSE REACTIONS, contact the CSL Behring Pharmacovigilance Department at 1-866-915-6958 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch***.**

----------USE IN SPECIFIC POPULATIONS----------

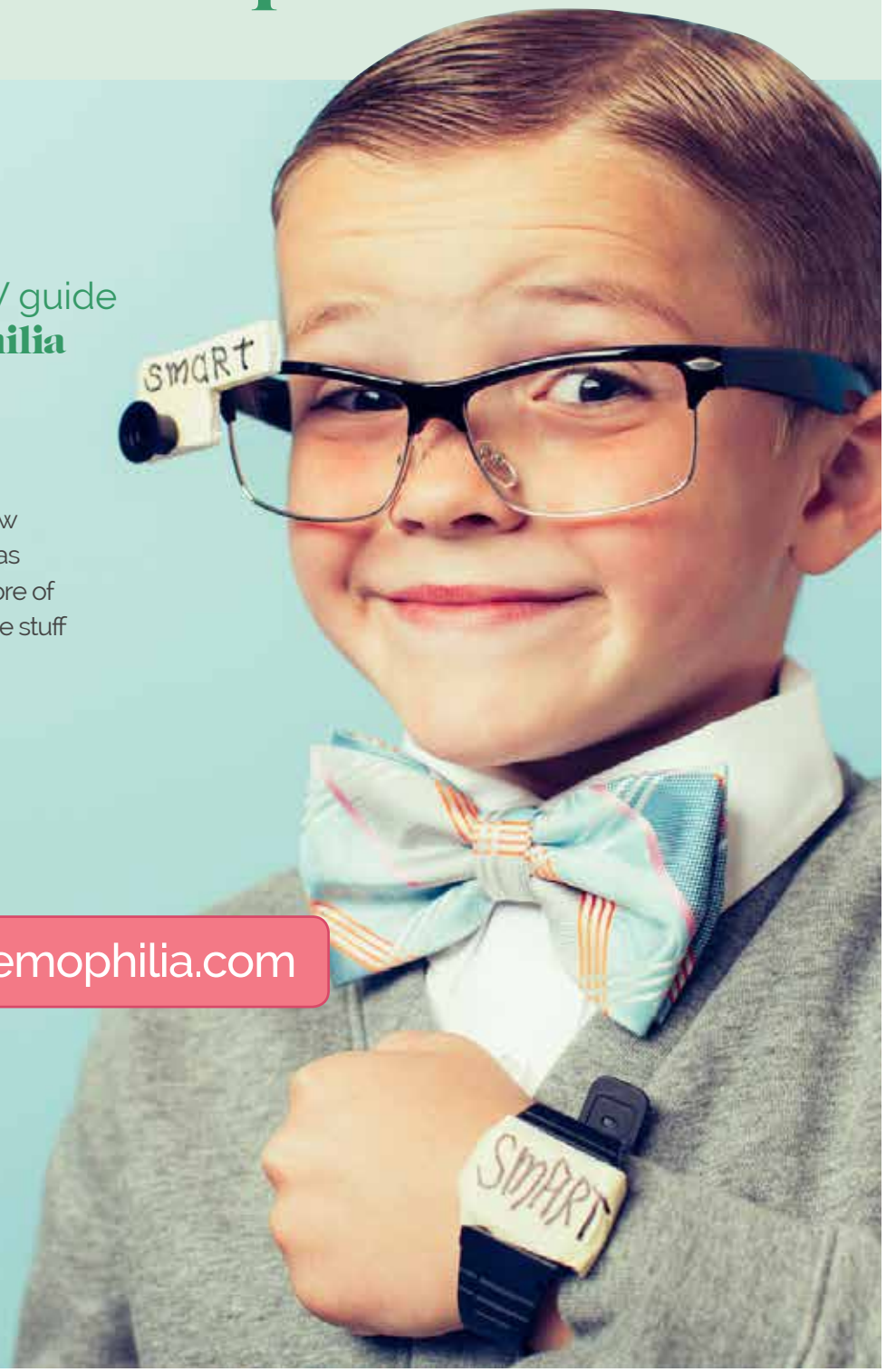
- Pediatric: Clearance (based on per kg body weight) is higher in pediatric patients 0 to <12 years of age. Higher and/or more frequent dosing may be needed.

Based on May 2016 version

BAYER

LIVING! with HEMOPHILIA

Looking for a new, fresh perspective on living with hemophilia?

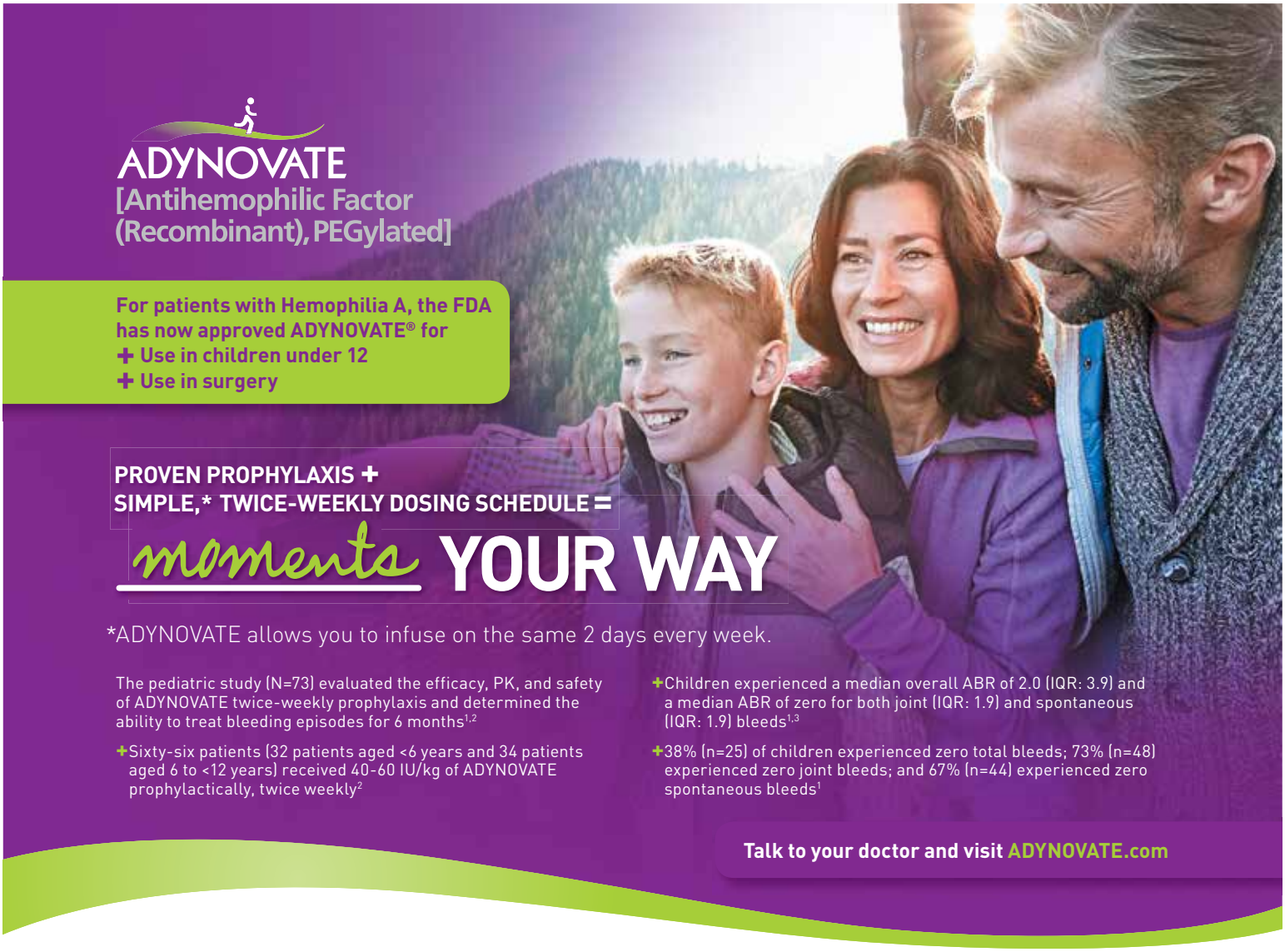


Introducing your all NEW guide to **Living With Hemophilia**

Discover the new online destination for learning about hemophilia, living a healthy life and even leading in the hemophilia community. It's all at the new **LivingWithHemophilia.com**. Our site has been totally redesigned to give you more of the information you want and less of the stuff you don't want.

See What's New at

www.LivingWithHemophilia.com



ADYNOVATE
[Antihemophilic Factor (Recombinant), PEGylated]

For patients with Hemophilia A, the FDA has now approved ADYNOVATE® for
+ Use in children under 12
+ Use in surgery

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

moments YOUR WAY

*ADYNOVATE allows you to infuse on the same 2 days every week.

The pediatric study (N=73) evaluated the efficacy, PK, and safety of ADYNOVATE twice-weekly prophylaxis and determined the ability to treat bleeding episodes for 6 months[1,2]

+Sixty-six patients (32 patients aged <6 years and 34 patients aged 6 to <12 years) received 40-60 IU/kg of ADYNOVATE prophylactically, twice weekly[2]

+Children 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[1,3]

+38% (n=25) of children experienced zero total bleeds; 73% (n=48) experienced zero joint bleeds; and 67% (n=44) experienced zero spontaneous bleeds[1]

Talk to your doctor and visit ADYNOVATE.com

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

Indications

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.

DETAILED IMPORTANT RISK INFORMATION

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.

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 ADYNOVATE 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 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.

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.

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.

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 ADYNOVATE Important Facts.

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

References: 1. ADYNOVATE Prescribing Information. Westlake Village, CA: Baxalta US Inc. **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; Shire US Inc.

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Shire

ADYNOVATE [Antihemophilic Factor (Recombinant), PEGylated]

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).

What are the possible side effects of 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.

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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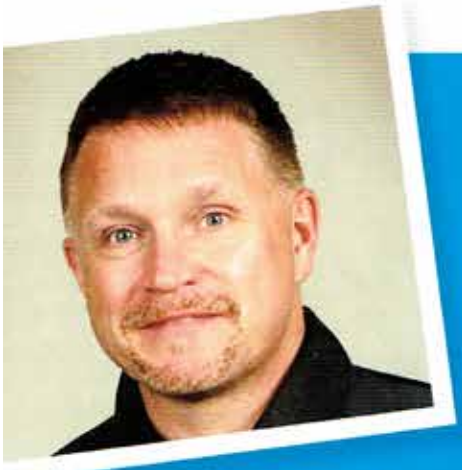
Pfizer Hemophilia

DEDICATION AND PERSONAL SUPPORT

The Patient Affairs Liaison role was created based on community feedback about the importance of helping to connect patients and caregivers with Pfizer Hemophilia tools and resources.

PATIENT AFFAIRS LIAISONS



Working for you—From the home of Motown to the Bluegrass State

Name: Chris Liddell

Home state: Michigan

Fun fact: If I'm watching TV, it's most likely sports-related. Go Tigers!

Ideal vacation spot: Anywhere quiet, unplugged from all electronics

What past experiences can you bring to this job? I've worked in hemophilia for over 10 years, so I've collaborated with and advocated for different members of this community.

To get in touch with Chris, call
Pfizer Hemophilia Connect 1.844.989.HEMO(4366)

What we do:

- Provide helpful information about Pfizer Hemophilia programs and services
- Serve as a resource to hemophilia treatment centers to help patients obtain access to Pfizer medicines
- Serve as a primary point-of-contact for local advocacy groups
- Participate in local and national events and programs
- Upon request, meet with patients and caregivers to answer questions related to Pfizer Hemophilia resources

"IT'S IMPORTANT TO CONNECT ON ALL LEVELS: HTCs, PATIENTS, FAMILIES, THE WHOLE COMMUNITY."

—Chris Liddell

Pfizer

Pfizer Hemophilia

You may be eligible for a one-time, 1-month supply up to 20,000 IU of factor from Pfizer Hemophilia at no cost.

For first-time use by commercially insured patients only. Terms and conditions apply.*

Scan the QR code or go to PfizerHemophiliaResources.com, download the discussion guide, and bring it to your next health care provider visit.

*Terms and conditions apply. Visit www.hemophiliavillage.com for complete terms and conditions. You must be currently covered by a private (commercial) insurance plan. For questions about the Pfizer Hemophilia Trial Prescription Program, please call 1-800-710-1379 or write us at Pfizer Hemophilia Trial Prescription Program Administrator, MedVantx, PO Box 5736, Sioux Falls, SD 57117-5736. If you are not eligible for the trial prescription program, you may find help accessing Pfizer medicines by contacting Pfizer's RxPathways™ program at 1-888-327-7787.

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June 2014

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