Fall 2016

KHF hemosphe

richard's review Richard J. Atwood

Remembering Fathers in Hemophilia: Samuel Appleton

I search for intriguing stories about people with bleeding disorders. By discovering those stories, including historical ones, I always learn something valuable. Often, I find inspiration in the stories of other family members, as in the case of the Appletons, who were connected with the powerful origins of our country.

One father of a child with hemophilia was Major Samuel Appleton (1625–1696). His son, Oliver Appleton, was the first person identified with hemophilia to be born in the American colonies.¹ Samuel spent a lifetime in public service fulfilling legislative, judicial, and military roles. He stuck to his principles about the illegality of improper taxation, and he remained calm in times of distress-during battle, and during the infamous Salem witch trials.

Samuel was only 11 when his family left England to settle in the Massachusetts Bay Colony in 1636. His father, also named Samuel, was one of the original settlers of historic lpswich. The family owned a house and eight acres in town, and a 400-acre farm on the Ipswich River.²

One of five children, Samuel grew up to help run the family farm and businesses. He married Hannah Paine in 1651, and they had three children. After his wife's death, in 1656 he married Mary Oliver (1640-1698), a hemophilia carrier, and had eight more children, including Oliver in 1677. Oliver's bleeding disorder was noted by family members, but probably not as a genetic condition. Only later, in retrospect, did family members realize the distinctness of the bleeding.

Due to periodic threats of Indian attacks, Samuel Appleton led the local militia. From lieutenant in 1668, he rose to the rank of captain during King Philip's War, and commanded an infantry of 100 men. At the decisive battle near Hatfield along the Connecticut River in 1675. Samuel was commander-in-chief of more than 500 men. A turning point for the colonists, this battle proved that the Indian warriors could be defeated. During the fighting, a bullet passed through Samuel's hair. If he had died then, his son Oliver with hemophilia would never have been born.

Samuel held several elected offices. As a legislator, he was a commissioner of Essex County in 1668. He was a representative of the General Court from 1669 to 1680. And he served on the Governor's Council from 1681 to 1692. Appleton opposed the government of the colonial governor, Sir Edmond Andros. When in 1687 Andros levied a tax of one penny on a pound, the town of Ipswich refused to collect the tax, stating that it was against the rights of Englishmen for any... continued on the next page

See more Walk photos inside on pages 4 & 5



Special News

Remembering Fathers in Hemophilia: Samuel Appleton cont...



...taxes to be levied without consent of an assembly chosen by landowners, or "freeholders." An arbitrary and illegal warrant was issued for the arrest of Samuel and other leaders in the opposition to the tax. Samuel took refuge in Saugus, where he stood on a rock and denounced the government. A Massachusetts historical marker now acknowledges the site as "Appleton's Pulpit." Refusing to apologize, Samuel was imprisoned in November 1687. He petitioned in January for his release due to his age and weakness, but wasn't freed until March 1688, when he posted a 1,000-pound bond.

In 1689, during the coup of crown-appointed Governor Andros, Samuel and other leaders in the Massachusetts Bay Colony put Andros on a boat to the island prison in Boston Harbor. Colonial revolutionaries 100 years later simplified the opposition to taxes with the slogan "No taxation without representation." But it's important to remember that the ideas for the American Revolution began long before 1776: to be properly recognized, Ipswich adopted the motto "The Birthplace of American Independence 1687."

Samuel Appleton served on the judiciary. He was a deputy to the Massachusetts General Court from 1668 to 1681. As a member of the Council of Assistants from 1681 to 1686, Samuel attended the examination of accused witches in Salem on April 11, 1692. His role may have been minor; he isn't always listed as one of the seven judges. And apparently he did not serve as a judge in any of the trials that executed 20 alleged witches in 1692. On May 2, 1693, the first Supreme Court convened in Ipswich to try Andover residents charged with witchcraft. As a judge at that hearing, Samuel cleared everyone accused of witchcraft, ending the infamous witch trials and demonstrating his rationality. During the hysterical witchcraft proceedings in Salem, Oliver Appleton was a 15-year-old with hemophilia living at home in Ipswich.

The story of Major Samuel Appleton reveals essential information about colonial America. Some of our defining principles that we cherish today were sown by the colonists years before the revolution for independence. We need to honor those colonial leaders for their contributions, and remember that Major Samuel Appleton also raised a son with hemophilia.



1. "The Appletons: America's 'First Family' with Hemophilia." PEN, Nov. 2002.

2. That farm still exists today. Called Appleton Farms, it is the second oldest continuously run farm in America, now administered by the Trustees of Reservations, a nonprofit conservation organization in Massachusetts.

© 2016 LA Kelley Communications, Inc. Reprinted with permission. All rights reserved.





Potential Therapy Employs Addition by Subtraction Approach

Recent research suggests that a new understanding of furin, a common protein found in most cells, could have therapeutic implications for people with factor VIII deficiency, or hemophilia A. The new findings, "Circumventing Furin Enhances Factor VIII Biological Activity and Ameliorates Bleeding Phenotypes in Hemophilia Models," were published October 6, 2016, in the journal JCI (Journal of Clinical Investigation) Insight. The lead investigator of the study was Valder R. Arruda, MD, PhD, a hematology researcher at The Children's Hospital of Philadelphia. Arruda is also a faculty member of the Perelman School of Medicine at the University of Pennsylvania.

Until now, scientists understood that among its many roles, furin contributes to coagulation. Factor replacement therapies, including factor VIII (FVIII) in hemophilia A and factor IX (FIX) in hemophilia B, contain amino acids that identify and interact with furin as part of the clotting process. However, Arruda and his team have discovered that while the furin/FIX interaction is a key "clotting-contributor," furin may not be necessary for a healthy clot to form in people with hemophilia A. They made this discovery by first bioengineering a new variant FVIII protein designed so that it would not interact with furin. They then used that variant in gene therapy experiments in mice with severe hemophilia A, which triggered increased FVIII levels and improved clotting activity in the animals.

Collaborating on the study were investigators from the University of North Carolina (UNC) at Chapel Hill led by Timothy C. Nichols, MD. The UNC team used the same gene therapy on dogs with hemophilia A. They also observed decreased bleeding as a result. In addition, no unwanted immune response occurred from the therapy.

By omitting the furin component, researchers have found a novel way to streamline delivery of the genetic material. "In gene therapy, size matters," said Arruda. "It's important to reduce the gene package for FVIII to the smallest effective size." Deleting the furin-recognition portion both decreases the size of the gene therapy "payload" and enhances its benefits for treating hemophilia A, he added.

Further research is needed before clinical trials in people can be conducted, but the researchers are optimistic about furin's future. "Because this variant provides more efficient bleeding control than currently available replacement drugs, while avoiding immune reactions, this could address the unmet needs of hemophilia A patients worldwide," added Arruda. "It may also advance gene therapy for this disorder as well."

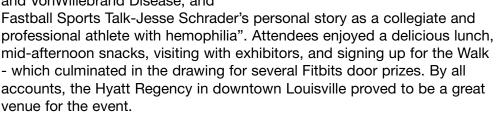
Event News

Annual Meeting

KHF's Annual Meeting was well attended by more than one hundred representatives of Kentucky's bleeding disorders community. Educational sessions offered information on a variety of topics, such as "Bullying Online and Offline, Spotlight on the



Unaffected Sibling, Genetics and VonWillebrand Disease, and



A Louisville Bats ballgame and dinner at the ballpark, sponsored by CSL Behring, concluded a successful day. We thank all of our day of event volunteers, especially Connie Thacker from Christian Fellowship for facilitating the Children's Activities. Sponsors and exhibitors for the event were Accredo, Baxalta-now part of Shire, Bayer HealthCare, Biogen, Cottrill's Pharmacy, CSL Behring, CVS Caremark, Emergent, Factor 4 Life, First Choice Home Infusion, Grifols, Matrix Health, Novo Nordisk, and Pfizer. We sincerely appreciate their support.



Gettin' in the Game



KHF nominated two young men to participate in CSL Behring's Gettin' in the Game Junior Championships in Phoenix, AZ this year. John Riley Graham from Winchester and Jackson Woods from Louisville. John Riley chose to try his hand at baseball and Jackson at golf. Both youngsters enjoyed these sports clinics/ championships and had a great time.

We thank CSL Behring for providing this recreational opportunity to boys and girls across the country who are living with the daily challenges of a bleeding disorder. Gettin' in the Game allows youngsters with bleeding disorders to experience the joys and benefits of being physically active and the realization that they can pursue and excel in sports.





Kentucky Hemophilia Walk

This year's Kentucky Hemophilia Walk took place on Saturday, October 8 at the same location as before, lovely Wetherby Park in Middletown. A warm and sunny day greeted our walkers as the various teams arrived from all corners of the state. Coffee and donuts were a welcome starter. Twenty-five teams gathered for a total of 169 walkers, not to mention all the little ones in strollers who also enjoyed the jubilant atmosphere and the kids activities. Kosair Funsters mixed and mingled with the crowd, our clown duo created balloon animals for the kids and painted artwork on their smiling faces. The





Event News

Walk cont...

bouncy monster truck and painting of gourds kept our youngest Walk participants quite happy. The adults hummed to our DJ's energizing tunes as they turned their rounds to be rewarded by tasty slices of Papa John's Pizza at the end. Door prizes for adults and kids delighted all winners.

The highlight of the event was recognizing all walk teams for their tremendous peer to peer fundraising efforts for the benefit of Kentucky's bleeding disorders community. We are pleased and so very appreciative to report that this year's Walk generated \$42,519, which significantly surpasses the proceeds of the first two Walks. Fifty-two percent of that amount was raised by our twenty-five teams, the remainder consists of corporate sponsorships.





Each of the top eight teams raised more than \$1,000, with the top team raising an astounding \$5,186. Honors and our gratitude for this commendable first place achievement, go to "Team Tag's Turtles" from Bowling Green as well as to "Team Brody" from Owingsville, who came in second with \$2,253 and "Team Jack!" from Louisville with \$1,645, who came in third. These winners received team awards and a commemorative prize for each team member.

The top three fundraisers for their respective teams were Tag Poynter, Team Captain of "Team Tag's Turtles with \$4,141; Brody Vanderpool, Team Captain of "Team Brody" with \$2,133; and Karen Lucky, Team Captain of "Team Levi" with \$1,352. These winners also received awards and prizes and and were able to claim incentive gifts after the Walk based on the amount they raised. Each walker who raised at least \$250 was eligible for an incentive gift. The more you raised, the nicer the gift.



There was palpable excitement among the Walk Teams when the results were announced and when their achievements were recognized. The Walk is a powerful and uplifting community event that brings Kentucky's bleeding disorders community together for the common good of a shared cause and to effect positive changes for the future of their children, grandchildren, and subsequent generations.

Thanks also go to all our sponsors, donors, and volunteers including Gold Sponsors Novo Nordisk and HEMA Biologics; Silver Sponsors CVS Caremark, CSL Behring, Octapharma, First Choice Home Infusion; Bronze Sponsor Kosair Charities; Kilometer Sponsors Matrix Health and Republic Bank; in-kind donors Papa John's Middletown Pizza, Option Care, Accredo, Heine Brothers Coffee, DJ/Axel Frol, Kosair Funsters, Barb Bitter, Cory Meadows, Walk Committee Chair, Venus Marcum; Christian Fellowship volunteers, Walk Committee members, and our dedicated day of event volunteers.



More News

Many Thanks To All 2015 – 2016 Annual Fund Donors For Their Generous Contributions

Challenge Gift, \$25,000

Forcht Bancorp Mr. & Mrs. Terry Forcht

Fundraisers Toward Meeting the Challenge, \$16,000+

Various Corporate Solicitations & Fundraising Activities 6th Annual KHF Strides for a Cure Relay Walk/Run

Forcht Challenge Donors, \$1,000 - \$2,000+

Don L. Mattingly David Hasch The Community Foundation of Louisville, Made possible by the Zoeller Company

Donors, \$250 - \$850

Chevron Matching Employee Funds Greg Fiscus Kroger Community Rewards Charles & Ruth Hall

Donors, \$100 - \$200

Dr. Joseph H. Cieslak Kathy Clay Clark County REMC Michael Gatton in honor of Greg Gatton Glen E. & Deborah Hitt Jennifer Hitt Humana Foundation John & Pat Tharp Calvin T. Zehnder

Donors, \$50 - \$99

Rebecca Daigrepont Anderson Harry & Cindy Clegg Shearer H. Fugate Stan Hankins Roger Harrell, Harrell Locksmith Janet & Bruce Masterson in memory of Regina Loeser Carol Nord Keith Peterson Brittany & Amanda Radice Rawlings Creative, Louisville Web Group Women of Immanuel, Immanuel UCC

Donors, Up to \$49

Amazon Smiles Benevity Community Impact Fund Eva A. Brenner Nancy S. Dudley G. Myers Trucking Curtis & Winnie Jacobs



Eric Hayes Carol Huddleston David & Terry Moore Clara Wheatley

<u>In Memory</u>

July 1, 2016 – October 31, 2016

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

Linda Sue Aswegan Lyman & Regina Brown Betty Humphrey Martha Hellige & Family Ida Scott Family

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

Outgoing Board Members

Two outgoing Board Members, whose terms expired after six years of service were recognized at the Annual Meeting in August. We thanked them for their service and commitment to our cause during their tenure and their contributions to moving the organization forward. Elizabeth Hart is retired from Henry County Schools but still works as a substitute teacher in Jefferson County because children are very dear to her and close to her heart. She served one year as President, one year as Vice President, and one year as Secretary. She is also a valued member of the Vegasville and Walk Committees, and we hope she will continue her participation.

Glen Hitt, Sr. is retired from Ford Motor Company but seems to be busy all the time with other "jobs" like golfing or unearthing gem stones with his wife Deborah. Glen is always willing to help. No request is too big or too small. Glen is an active and essential member of our Golf, Vegasville, and Walk Planning Committees, and we hope that he will continue in this role. We appreciate and thank them both very much!



More News

KHF awarded three \$500 post-secondary education scholarships for the fall 2016 semester



A scholarship donated by Sharen and Keith Harmon in memory of her mother, Martha Joyce Bennett Johnson, was awarded to Kevin Loeser. Kevin is the son of Ron and Myra Loeser and lives here in Louisville. Kevin attends the University of Louisville, where he majors in Accounting. Kevin is t-shirt commissioner and former chair of his fraternity and previously received a leadership award. Kevin expects to graduate with a Bachelor's degree in Accounting in May 2017.



The Terry D. Turner 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. She has been on the Dean's list for four consecutive semesters and is a member of the University of South Carolina Honors College. Emily expects to graduate with a Bachelor of Science degree in Biology in May 2017.



The Herb Schlaughenhoupt, Jr. 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 in Carrollton, where he majors in Elementary Education. Andrew was on the Dean's list for the spring 2016 semester and anticipates graduating in May 2020 with a Bachelor's degree.

New Board Members and Officers

Officers elected at the Annual Meeting in August for the current year are Deborah Hitt, President; Venus Marcum, Vice President; Brad Comer, Treasurer; and Sara Ceresa, Secretary. We thank these Board Members for their previous service as Directors and for their willingness and commitment to serve in these new roles as well. KHF is also welcoming two new Board Members, Cory Meadows and Bradley Woods. Cory holds the position of Director for Advocacy and Legal Affairs for the Kentucky Medical Association. His extensive work history includes working as a staff attorney for Frost Brown Todd as well as other law firms and holding management positions in the Governor's office for Local Development and the Kentucky Transportation Cabinet. When he is not working, he spends time with his family. Cory, his wife Whitney, and their son Jack reside in Louisville. We hope that Jack will eventually also attend our summer camp.

Bradley is a Project Manager for Advanced Business Solutions and has worked for Citi Cards and UPS. He has an Associate degree in Information Technology from the University of Phoenix. His skill set includes project management experience involving mergers and acquisition within the Kentucky healthcare market. Outside of work, he enjoys traveling, cooking, board games, swimming, and Dallas Cowboys football. Bradley, his wife Leah, and their three children live in Louisville. Their children Jackson and Izzi are regulars at our summer camp.

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.



Vegas is coming to the 'Ville **February 25, 2017**









Non Profit Org. U.S. Postage PAID Louisville, KY Permit No. 883





Watch the videos at

PatientIXperiences.com

Manufactured by Cangene Corporation, a subsidiary of Emergent BioSolutions Inc. and distributed by Cangene bioPharma, Inc., a subsidiary of Emergent BioSolutions Inc.

IXINITY [coagulation factor IX (recombinant)], IXperience, and any and all Emergent BioSolutions Inc. brand, product, service and feature names, logos, slogans are trademarks or registered trademarks of Emergent BioSolutions Inc. or its subsidiaries in the United States or other countries. All rights reserved.



© 2016 Emergent BioSolutions Inc. All rights reserved. CM-FIX-0027

IXINITY[®]

coagulation factor IX (recombinant)

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.

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.

Development of procoagulant activity-neutralizing antibodies (inhibitors) has been detected in patients receiving FVIIIcontaining 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.



Learn more at alphanate.com



access solutions



Don't let insurance or financial challenges get between you and your treatment

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

Live Helpline Support

- 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.

⁶People 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.

Bayer and the Bayer Cross are registered trademarks of Bayer. © 2016 Bayer. All rights reserved. Printed in USA 03/16 PP-775-US-0156



THE FIRST FACTOR VIII WITH A PROLONGED HALF-LIFE

Learn how a prolonged half-life may affect your infusion schedule

Meet your CoRe Manager Carol DeMatteis E: carol.dematteis@biogen.com T: 330-730-1975

Indications

ELOCTATE, [Antihemophilic Factor (Recombinant), Fc Fusion Protein], is a recombinant DNA derived, antihemophilic factor indicated in adults and children with Hemophilia A (congenital Factor VIII deficiency) for: on-demand treatment and control of bleeding episodes, perioperative management of bleeding, and routine prophylaxis to reduce the frequency of bleeding episodes. ELOCTATE is not indicated for the treatment of von Willebrand disease.

Important Safety Information

Do not use ELOCTATE if you have had an allergic reaction to it in the past.

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, are breastfeeding, are pregnant or planning to become pregnant, or have been told you have inhibitors (antibodies) to Factor VIII.

Allergic reactions may occur with ELOCTATE. 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 ELOCTATE, which may stop ELOCTATE from working properly.

The most frequently occurring side effects of ELOCTATE are headache, rash, joint pain, muscle pain and general discomfort. These are not all the possible side effects of ELOCTATE. Talk to your healthcare provider right away about any side effect that bothers you or that does not go away, and if bleeding is not controlled after using ELOCTATE.

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.



FDA-Approved Patient Labeling Patient Information ELOCTATE[®] /el' ok' tate / [Antihemophilic Factor (Recombinant), Fc Fusion Protein]

Please read this Patient Information carefully before using ELOCTATE 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 ELOCTATE?

ELOCTATE is an injectable medicine that is used to help control and prevent bleeding in people with Hemophilia A (congenital Factor VIII deficiency).

Your healthcare provider may give you ELOCTATE when you have surgery.

Who should not use ELOCTATE?

You should not use ELOCTATE if you had an allergic reaction to it in the past.

What should I tell my healthcare provider before using ELOCTATE?

Talk to your healthcare provider about:

- Any medical problems that you have or had.
- All prescription and non-prescription medicines that you take, including over-the-counter medicines, supplements or herbal medicines.
- Pregnancy or if you are planning to become pregnant. It is not known if ELOCTATE may harm your unborn baby.
- Breastfeeding. It is not known if ELOCTATE passes into the milk and if it can harm your baby.

How should I use ELOCTATE?

You get ELOCTATE as an infusion into your vein. Your healthcare provider will instruct you on how to do infusions on your own, and may watch you give yourself the first dose of ELOCTATE.

Contact your healthcare provider right away if bleeding is not controlled after using ELOCTATE.

What are the possible side effects of ELOCTATE?

You can have an allergic reaction to ELOCTATE. Call your healthcare provider or emergency department 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 ELOCTATE. This can stop ELOCTATE from working properly. Your healthcare provider may give you blood tests to check for inhibitors. Common side effects of ELOCTATE are headache, rash, joint pain, muscle pain and general discomfort.

These are not the only possible side effects of ELOCTATE. Tell your healthcare provider about any side effect that bothers you or does not go away.

How should I store ELOCTATE?

- Keep ELOCTATE in its original package.
- Protect it from light.
- Do not freeze.
- Store refrigerated (2°C to 8°C or 36°F to 46°F) or at room temperature [not to exceed 30°C (86°F)], for up to six months.
- When storing at room temperature:
- Note on the carton the date on which the product is 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 ELOCTATE after the expiration date printed on the vial or, if you removed it from the refrigerator, after the date that was noted on the carton, whichever is earlier.

After reconstitution (mixing with the diluent):

- Do not use ELOCTATE if the reconstituted solution is not clear to slightly opalescent and colorless.
- Use reconstituted product as soon as possible.
- You may store reconstituted solution at room temperature, not to exceed 30°C (86°F), for up to three hours. Protect the reconstituted product from direct sunlight. Discard any product not used within three hours.

What else should I know about ELOCTATE?

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

44279-02

Manufactured by: Biogen Inc. Cambridge, MA 02142 USA U.S. License # 1697 ELOCTATE® is a registered trademark of Biogen.

Biotherapies for Life[®] CSL Behring

OAFSTYLA® Antihemophilic Factor (Recombinant), Single Chain

Visit AFSTYLA.com today

 $(\square) (m) (\bigcirc) (\$)$

SHIRE'S COPAY ASSISTANCE PROGRAM

 \cap

Are you eligible to save up to \$12,000* every 12 months?

Shire's CoPay Assistance designed for you!

Let us help you pay for your out of pocket medication costs in 3 simple steps.

- 1. Call us at 1-888-229-8379.
- 2. Answer a few simple questions, and let Shire handle the rest
- 3. Receive eligibility information in the mail.

* Full terms and conditions apply. Call 1-888-229-8379 or visit www.hematologysupport.com for more information.

We've got you covered

Call 1-888-229-8379 or visit www.hematologysupport.com.

© 2016 Shire US Inc., Lexington, MA 02421. All rights reserved. 1-800-828-2088. SHIRE and the Shire Logo are registered trademarks of Shire Pharmaceutical Holdings Ireland Limited or its affiliates. We've got you covered is a trademark or registered trademark of Baxalta Incorporated, a wholly owned, indirect subsidiary of Shire plc. USBS/MG155/15-0007(2) 09/16





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.

Pfizer

Marketed by Pfizer Inc.

June 2014

coagulation factor IX

(recombinant)

Manufactured by Wyeth Pharmaceuticals Inc.

HEM660401-03 © 2014 Pfizer Inc. All rights reserved.





a subsidiary of Emergent BioSolutions Inc IXINITY [Coagulation Factor IX (Recombinant)], IXperience, B More, and any and all Emergent BioSolutions Inc. brand, product service and feature names, logos, slogans are trademarks or registered trademarks of Emergent BioSolutions Inc. or its subsidiaries in the United States or other countries. All rights reserved. © 2015 Emergent BioSolutions Inc.

IXI 136-0915

INTRODUCING IDELVION NOW AVAILABLE

IDELVION is manufactured by CSL Behring GmbH and distributed by CSL Behring LLC. IDELVION® is a registered trademark of CSL Behring Recombinant Facility AG. Biotherapies for Life® is a registered trademark of CSL Behring LLC. ©2016 CSL Behring LLC 1020 First Avenue, PO Box 61501,

King of Prussia, PA 19406-0901 USA www.CSLBehring-us.com www.IDELVION.com IDL16-03-0070 3/2016

