Hispanic Heritage Month Event
a Rousing Success!

NEHA hosted the 2nd Annual Hispanic Heritage Month event in October at the Holiday Inn Bunker Hill in Somerville, Massachusetts. The event was a rousing success! Feedback from families included “everything was magnificent” and “the themes were very educational.” While the parents were attending educational sessions, the youth had a field trip to the Museum of Science! There was also a late night game of dominos with the dads and several families went swimming at the indoor pool.

NEHA appreciated the support from several of our pharmaceutical partners; Novo Nordisk, CSL Behring, Biogen, Pfizer, Baxalta, Bayer, and CVS Health for exhibiting and presenting at the conference. In addition, HFA had an excellent presentation by Maria Santaella, RN, MSN, CPHON, about the Psycho-social Aspects of Infusion.

The Hispanic Heritage Month Event is a wonderful opportunity to connect our Spanish speaking population and to provide support, education and advocacy in their native language. We hope to offer it again next fall and continue the tradition!
Dear NEHA Member,

The never ending pursuit of balance seems to be one of the challenges that we continue to be faced with. One important aspect of balance in our NEHA world is the continuous challenge of meeting the ever changing needs of our community and our organization.

By the time you read this you will already know that Kevin Sorge, our Executive Director has left NEHA to pursue new opportunities. For the last eight years, Kevin has taken steps to build an outstanding, rock solid organization that continues to be recognized as a leading chapter across the national Hemophilia landscape. During his time, Kevin more than doubled NEHA’s budget, hired an “invincible” staff, and created new opportunities for our industry partners to participate and bring innovative programming and ideas to NEHA. Many thanks to Kevin, I am confident there will be bigger and brighter opportunities ahead!

In the month of December and early January we are planning to post the position of Executive Director to standard commercial job sites where any and all qualified candidates can apply–this may include you! Please monitor the NEHA Facebook page for more details–our goal is to have the position filled early in February as our board will be holding a strategic planning session early spring which our new ED will play a major role. Prior to this, we will be circulating some survey materials for the community to assist in that effort.

Despite the fact that our fiscal year ends in September, December is still a time of reflection when we evaluate our overall efficacy throughout the calendar year and duly count our blessings. I want to express a sincere and heartfelt thanks to our staff, supporters, industry partners, and board members for their incredible altruism and kindness and most especially, personal commitment – without it our organization could never diversify and grow as it has so successfully.

Best wishes to one and all for a Happy and safe holiday season!

Sincerely,

Pat Mancini
NEHA President
**Parenting Tips to Raise a Healthy Child with a Bleeding Disorder!**

*by Shari Bender*

**Tip #1: IF IN DOUBT, INFUSE**

It was Nana’s 75th birthday party and it was a big deal. Rose had just turned two and she was making her debut in the extended family as the first-born great grandchild. It was a bit of a trek to the catering hall in Queens from our home on Long Island. We packed toys, games, wipes and other toddler necessities. But we didn’t pack the factor. I rationalized that it was safe and I could keep an eye on Rose, that she wouldn’t get hurt and we’d pretend hemophilia didn’t exist, just for the duration of Nana’s party.

**Hemophilia had other plans.**

Nana’s party was complete with a DJ and an inviting dance floor. Rose had played all the games we had packed, tried all the new foods and she was ready to dance. And it was so much fun! Rose danced and twirled, and we were all having a blast until in supreme toddler fashion -- Boom! Rose slipped and hit her head on the unforgiving wooden dance floor. A wave of panic swept through me: How could we leave Nana’s party? We whisked Rose away, trying to slip away unnoticed. We called my in-laws who met us at the local hospital with factor to infuse Rose. So, Dance Floor meets Toddler’s Head is an obvious Infuse Moment. What about for those less obvious times, those “Should we infuse for this?” moments. These moments often come right before the bus is coming or at midnight, or at any other time in the day where you just don’t have the time or energy to infuse. I cannot emphasize this enough: If you are asking yourself whether to infuse your child for an injury or even for a "feeling," do it.

*If in doubt, infuse.*

Infuse when your child comes home from a concert and has a forearm bleed from excessive clapping, infuse when a spirited game of foosball has triggered an elbow bleed, and infuse for that "off" feeling in your child’s hip, where if left untreated it could turn into a full-fledged and debilitating hip bleed. Even if your child is on prophylaxis he or she can have breakthrough bleeds, so it is important not to brush off any symptoms of a bleed.

As Rose got older, we infused smarter. Even on prophylaxis we would change the days to protect her when her activity level was higher. Some not-so-obvious times to infuse: before a sleepover, before a major holiday, and even, yes, a birthday infusion. And always bring factor and supplies if you are heading more than an hour away from home. With a proactive approach, you and your child will be able to hit the dance floor at Nana’s party. And stay the whole time.

*Be safe, Have fun*

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**Pumpkin Fest benefits NEHA**

At Laconia’s first annual Pumpkin Fest in October, Preston Kennell and his sister Vivian wanted to raise some money for hemophilia. They decided to sell pumpkin hats out in front of their dad’s orthodontic office- right down the street from all of the Pumpkin Fest activities. The Kennell’s also offered paid parking for the event, with proceeds benefitting NEHA. The final result was a fantastic donation of $1,000 to help NEHA in improving the lives of people with bleeding disorders! Many thanks for Preston and Vivian for their efforts in turning a fun event into a fundraiser for NEHA!
Infusion of Humanitarian Aid to Help Sustain Hemophilia Treatment in Developing World

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

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

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

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

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

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

Source: Joint press release from WFH, Biogen, and Sobi; October 12, 2015.
At last! I am not traveling, and I have time to attend the hemophilia events in my own back yard. This one is Fall Fest, New England Hemophilia Association’s biannual event. Held in charming Providence, Rhode Island, we had about 100 people attending to hear speakers like Barry Haarde, who rode a bike across the US four times; Dawn Rotellini of NHF; and Perry Parker, golf pro. I consider all these speakers not only interesting, but also friends! In fact, and I know this isn’t original, but it really was like a family reunion, to be surrounded by so many friends and families, some of whom I’ve known for 15 or 20 years.

The general session opened the day, with guest speaker Dr. Kapil Saxena, Director, Global Clinical Leader, Global Clinical Development, Hematology, of Bayer Corporation, formerly a pediatric hematologist with the Boston Hemophilia Treatment Center. He spoke about how a drug like factor is brought to market. It was excellent and informative, and stunning. Some highlights:

Every drug on the market starts as one of almost 10,000 compounds. Which one has a chance to be brought to market one day? The Drug discovery journey sorts through those 10,000 compounds, to narrow the field to 259 compounds (this can take up to 6 years). These are furthered narrowed to 5 compounds (another 6 years!), which then are brought to the FDA for review. When approved, they go into clinical studies, which can last up to 1.5 years. Altogether, a drug like factor can take almost 14 years to get to the market.

(Read http://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs/)

Dr. Saxena explained the stages of clinical studies. There are four stages, and some get killed off in the first stage, Phase I, for safety reasons. Phase II examines efficacy and safety. Phase III, if it makes it that far, involves a large number of patients, from 1,000-3,000 (although that can’t possibly be true for hemophilia). More data is gathered over many clinical centers. For hemophilia, these involve sites now in India, Egypt, China and more. After the drug is brought to market, Phase IV looks for any more problems, now that the drug is in widespread use.

His talk was relevant to our hemophilia marketplace today. With the patents expired on factor VIII, IX and FVII molecules, our R&D and production pipelines are filled with new products. Pharmaceutical companies are banking on selling these, and yet the marketplace is getting crowded. Dr. Saxena’s talk really made us think about the extraordinary effort—and cost—that goes into making any one hemophilia product. On the one hand, these are among the most scrutinized products on earth, and that’s great. On the other, how will the market sustain all these great products? It will be interesting to monitor and to check in a year from now.

The afternoon sessions were a bit lighter! I attended one starring—I mean featuring Barry Haarde! Of course, Barry is pretty much a celebrity by now in this community for his heroic rides across America. Six weeks after completing a 108 mile ride in one day, I still am having severe shoulder pain. Barry does that in a day, and then goes out and does another 100, then another, then another… he’s Superman! He and Christian Mund, a young man with hemophilia, spoke on setting goals, making dreams come true. Christian lives right near me and I’ve known him since he was 12. And he went his first 12 years without being involved in the community at all. Why? Life was good; there was factor, prophy, and no need! But as he got involved, he enjoyed the rich relationships and friends he made. He went through Bayer’s Leadership program, and landed an excellent job at a marketing firm in Boston! Way to go!

Barry shared his story about how he got involved too. Barry went most of his adult life without being involved. Shielding his HIV/hep C positive status from everyone kept him from making connections. But he eventually joined our community when his brother passed away. And boy did Barry join it! No one in the US can compete with Barry on the cycling front. He’s made history at this point, and raised about $170,000 for my nonprofit Save One Life. But his message was simple: find what you can do and love to do. You’ll never know where it will lead.

The day finished off with a dynamic presentation by CoRe managers from Biogen, and also community
The National Hemophilia Foundation (NHF) is pleased to announce the 2015 winners of the Josh Gordy Educational Scholarship: Lynden Prior, 20, from Shelburne, Vermont; and Darian Ross, 19, from North Dartmouth, Massachusetts. Josh Gordy is an American football cornerback for the New York Giants, a National Football League (NFL) team. Josh created this scholarship in honor of his nephew, Nolan, age 13, who has severe hemophilia A with inhibitors.

The scholarship grants two awards of $1,000 each, which can be used to pay expenses related to undergraduate studies at a 2- or 4-year accredited college or university. Those chosen must demonstrate strong service to the community. Other factors that are considered include achievements, personal essay and letters of recommendation.

About this year’s scholarship winners:

Lynden Prior has displayed exceptional service and leadership both within and outside the bleeding disorders community. He has been involved in the New England Hemophilia Association’s (NEHA) family camp, SpringFest and FallFest, as a speaker and helping fundraise. He also was active in Amnesty International, the Salvation Army soup kitchen and as dorm president at the University of Vermont. Lynden is majoring in microbiology and molecular genetics in hopes to one day continue the field of research to help improve the lives of people living with bleeding disorders.

Darian Ross has also demonstrated excellence in service through his leadership roles in NEHA’s Camp High Hopes and SpringFest, as well as the Hemophilia Federation of America’s Gears for Good Bike Ride, the Hole in the Wall Gang Camp and the Connecticut Hemophilia Society. He teaches Tae Kwon Do and Brazilian Jiu-Jitsu to children. Darian has a passion for cars and is working to attain his associate’s degree as an automotive service technician to then go on to obtain his bachelor’s degree.

NHF wishes them the best of luck in their academic success and future endeavors!

To Market, To Market (Continued from page 5)

members: Lee Hall, person with hemophilia, and Lisa Schmidt, former program manager for NEHA. It was inspiring and fun. I’m not going to give away their presentation, because… you should go yourself! I give presentations, and know all the tricks and topics, been doing this for 25 years. But I learned a few really wonderful things at this presentation.

We had to hustle out the Omni as the Redskins were approaching for their game with the Patriots! Like Rhode Island, the hotel was kind of small, so we headed home, really feeling happy after spending a day with “family.”

Re-printed with permission
In mid-October, NEHA hosted a women’s retreat at the Wylie Inn and Conference Center in Beverly, MA. Forty women and teens met for “The Female Connection: Bringing Together Female Patients, Caregivers, and Carriers.” The event was supported by an educational grant from CSL Behring.

The retreat opened with a dinner and a sharing activity where participants were asked to write their own source of strength on a rock. The rocks were then collected to illustrate our collective strength and to highlight our resiliency as a community.

After a full breakfast in the conservatory overlooking the ocean, there was a general session given by Dr. Stacy Croteau, Associate Director of the Boston Hemophilia Treatment Center, Finding A Voice, Defining the Challenges: Impact of Bleeding Disorders on Women and Girls.

Attendees then had the option of several rap sessions; The Importance of Self-Advocacy led by Kristin Prior, Parenting and Bleeding Disorders led by Bonnie Boomsma-Hall, or Girl Talk- Empowering Girls, Increasing Self-Esteem and Understanding Transitions of Life led by Tori Tiger, CSL Consumer Teen Advocate.

Dr. Henry Mead, Medical Affairs Director at CSL Behring, shared a von Willebrands update with all attendees after lunch. Afternoon breakout sessions were led by Lynne Szott, CSL Reimbursement Manager; Dr. Amanda Kallen, MD at Yale Medical Center; and Tori Tiger.

The conference concluded with two health and wellness workshops; Eating Right for Good Nutrition and Stress Management and Yoga.

NEHA received overwhelming positive feedback about the conference. Comments included “It was incredibly informative about vWD! THANK YOU! I really liked the educational sessions and high quality of speakers.” “Sessions were excellent! Great mix and balance of information and interaction.” Stay tuned for information about next year’s conference planning is already underway!
The US Food and Drug Administration (FDA) recently approved Octapharma’s new therapy NUWIQ®, for the treatment of bleeding in children and adults with hemophilia A. The product is indicated for on-demand treatment and control of bleeding episodes; routine prophylaxis to reduce the frequency of bleeding episodes; and perioperative management of bleeding. According to Octapharma, NUWIQ® is the first B-domain deleted recombinant factor VIII derived from a human cell-line. The therapy is cultured without using additives of human or animal origin, and is not chemically modified or fused with another protein.

The FDA’s approval of NUWIQ® was granted in light of several successful global studies demonstrating the product’s pharmacokinetics (PK), efficacy and tolerability. A multi-center PK clinical trial of previously treated patients (PTPs) with hemophilia A showed a mean half-life of 17.1 hours in adults, 11.9 hours for children ages 2 to 5, and 13.1 hours for children ages 6 to 12.

A subsequent series of clinical studies measured overall efficacy and tolerability of NUWIQ® in 135 adult and pediatric PTPs with severe hemophilia A. Overall, these patients were treated with a total of 16,134 infusions of the product over 15,950 exposure days. One study rated NUWIQ®’s prophylactic efficacy in 32 adults and found that the product’s capacity to control spontaneous bleeds was “excellent or good” in 92% of the participants. In another study, prophylactic efficacy for spontaneous bleeds was rated as excellent or good in 97% of the 59 pediatric patients enrolled.

“Early development strategies were integral in the development of NUWIQ® and these initial goals have been realized with the FDA approval,” said Octapharma USA President Flemming Nielsen. “NUWIQ® has demonstrated safety and efficacy in global clinical trials and has the potential to positively impact patients’ quality of life in the years ahead.”

The US Food and Drug Administration (FDA) approved Coagadex®, Coagulation Factor X (Human), for hereditary factor X (FX) deficiency. Until today’s orphan drug approval, no specific coagulation factor replacement therapy was available for patients. In healthy individuals, the FX protein activates enzymes to help with normal blood clotting in the body. FX deficiency is an inherited disorder affecting men and women equally in which the blood does not clot as it should. Patients with the disorder are usually treated with fresh-frozen plasma or plasma-derived prothrombin complex concentrates (plasma products containing a combination of vitamin K-dependent proteins) to stop or prevent bleeding.

The availability of a purified FX concentrate increases treatment options for patients with this rare bleeding disorder.

“The approval of Coagadex is a significant advancement for patients who suffer from this rare but serious disease,” said Karen Midthun, MD, director of the FDA’s Center for Biologics Evaluation and Research.

Coagadex, which is derived from human plasma, is indicated for individuals aged 12 and older with hereditary FX deficiency for on-demand treatment and control of bleeding episodes, and for perioperative (period from hospitalization for surgery to the time of discharge) management of bleeding in patients with mild hereditary FX deficiency.

The safety and efficacy of Coagadex were evaluated in a multi-center, nonrandomized study involving 16 participants (208 bleeding episodes) for treatment of spontaneous, traumatic and heavy menstrual (menorrhagic) bleeding episodes. Coagadex was demonstrated to be effective in controlling bleeding episodes in participants with moderate to severe hereditary FX deficiency. It was also evaluated in five participants with mild to severe FX deficiency who were undergoing surgery. The five individuals received Coagadex for perioperative management of seven surgical procedures. Coagadex was demonstrated to be effective in controlling blood loss during and after surgery in participants with mild deficiency. No individuals with moderate or severe FX deficiency received Coagadex for perioperative management of major surgery, and no safety concerns were identified in either study.

The FDA granted Coagadex orphan product designation for these uses. Orphan product designation is given to drugs intended to treat rare diseases in order to promote their development. Coagadex was also granted fast track designation and priority review.

Coagadex is manufactured by Bio Products Laboratory Limited in Elstree, Hertfordshire, United Kingdom.
Great Fun at the NEHA Holiday Party!
Across the country, HFA has heard of many cases of patients and their families facing new limitations and restrictions from their insurance services like prior authorization, step therapy policies, and restrictions on which specialty pharmacy or pharmacy benefits manager (PBM) may be used. HFA speaks with individuals weekly who struggle to obtain needed exceptions to rules and policies from their service providers. Receiving temporary exceptions serves that particular family or situation but exceptions can be reversed without input or prior notice, and may only last a short time, needing constant renewal. Policy or rule changes provide more overall protection for the entire community. As a community advocacy organization, HFA recognizes the need to obtain policy changes for families with bleeding disorders. To do so, we need to present a unified request with multiple examples of how a current rule or policy is not effective or may possibly harm patients.

To address these concerns, HFA has developed Project CALLS [Creating Alternatives to Limiting and Lacking Services], a patient-centered initiative which invites members of the community to share their individual stories about insurance issues to help the entire bleeding disorders community. Project CALLS is flexible in accommodating those who wish to participate. Depending on their preference, participants may speak privately with a trained member of the HFA staff or complete an online form regarding their insurance concerns.

Through the gathering of these stories, HFA will identify trends and collate data to build a broad case for change then work with other advocates, insurance companies, pharmacies and other providers to request needed changes. The information may also be used to educate insurers, legislators, and human resource departments about more comprehensive, cost-effective ways to provide quality care for individuals with bleeding disorders.

**Project CALLS is designed for individuals or families who have been:**

- Denied services or have received an exception;
- Forced by an insurance company to “fail” on a product before being allowed to use the product of their choice;
- Mandated to use a pharmacy that is not meeting their needs, and/or;
- Forced to go through a lengthy pre-/prior-authorization process

Your Voice Really Matters!

Like our CHOICE survey, Project CALLS is the latest way that HFA is listening to our community’s needs. HFA has been able to turn the results of CHOICE into action with Project RED and our Bleeders’ Bill of Rights. Project CALLS is the next step in helping individuals with bleeding disorders to receive the best care possible.

To participate in Project CALLS, visit the HFA website: [http://www.hemophiliafed.org/advocacy/project-calls/](http://www.hemophiliafed.org/advocacy/project-calls/) and share with others in the community.

Share your story through this very important initiative and be a part of a community that cares!
Leadership begins with U.
Apply for a summer internship with Bayer Healthcare!
Click here to apply.

Application Deadline is Friday, February 12, 2016 at 11:59 p.m. ET

Introducing Bayer Leadership U, a paid summer internship for full-time college students whose lives have been touched by hemophilia. Work alongside leaders at Bayer, while learning how to become a future leader in the hemophilia community.

Learn how to stand out in business and stand up for our community.

Selected interns will travel to Bayer's U.S. Headquarters in New Jersey* and will spend six weeks participating in activities that aim to help them grow personally and professionally.

Click here to learn more about Bayer Leadership U!

*Includes lodging and transportation costs

Interns will be selected based on application responses and an interview process. Applications are due no later than Friday, February 12, 2016 at 11:59 p.m. ET.

Explore Bayer Healthcare's additional leadership opportunities, Step Up Reach Out and AFFIRM, at www.hemophilialead.net
ADVATE
[Antihemophilic Factor (Recombinant)]

Important facts about
ADVATE [Antihemophilic Factor (Recombinant)]

This leaflet summarizes important information about ADVATE. Please read it carefully before using this medicine. This information does not take the place of talking with your healthcare provider and it does not include all of the important information about ADVATE. If you have any questions after reading this, ask your healthcare provider.

What is the most important information I need to know about ADVATE?
Do not attempt to do an infusion to yourself unless you have been taught how by your healthcare provider or hemophilia center.

You must carefully follow your healthcare provider’s instructions regarding the dose and schedule for infusing ADVATE so that your treatment will work best for you.

What is ADVATE?
ADVATE is a medicine used to replace clotting factor (factor VIII or antihemophilic factor) that is missing in people with hemophilia A (also called “classic” hemophilia). The product does not contain plasma or albumin. Hemophilia A is an inherited bleeding disorder that prevents blood from clotting normally.

ADVATE is used to prevent and control bleeding in adults and children (0–16 years) with hemophilia A.

Your healthcare provider may give you ADVATE when you have surgery. ADVATE can reduce the number of bleeding episodes in adults and children (0–16 years) when used regularly (prophylaxis).

ADVATE is not used to treat von Willebrand disease.

Who should not use ADVATE?
You should not use ADVATE if you:
• Are allergic to mice or hamsters.
• Are allergic to any ingredients in ADVATE.

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

How should I use ADVATE?
ADVATE is given directly into the bloodstream.

You may infuse ADVATE at a hemophilia treatment center, at your healthcare provider’s office, or in your home. You should be trained on how to do infusions by your healthcare provider or hemophilia treatment center. Many people with hemophilia A learn to infuse their ADVATE by themselves with the help of a family member.

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

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

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

What should I tell my healthcare provider before I use ADVATE?
You should tell your healthcare provider if you:
• Have or have had any medical problems.
• Take any medicines, including prescription and non-prescription medicines, such as over-the-counter medicines, supplements or herbal remedies.
• Have any allergies, including allergies to mice or hamsters.
• Are breastfeeding. It is not known if ADVATE passes into your milk and if it can harm your baby.
• Are pregnant or planning to become pregnant. It is not known if ADVATE may harm your unborn baby.
• Have been told that you have inhibitors to factor VIII (because ADVATE may not work for you).

What are the possible side effects of ADVATE?
You can have an allergic reaction to ADVATE.

Call your healthcare provider right away and stop treatment if you get a rash or hives, itching, tightness of the throat, chest pain or tightness, difficulty breathing, lightheadedness, dizziness, nausea or fainting.

Side effects that have been reported with ADVATE include:
• cough
• headache
• joint swelling/aching
• sore throat
• fever
• itching
• dizziness
• hematoma
• abdominal pain
• hot flashes
• swelling of legs
• diarrhea
• chills
• runny nose/congestion
• nausea/vomiting
• sweating
• rash

Tell your healthcare provider about any side effects that bother you or do not go away.

These are not all the possible side effects with ADVATE. You can ask your healthcare provider for information that is written for healthcare professionals.

What else should I know about ADVATE and Hemophilia A?
Your body may form inhibitors to factor VIII. An inhibitor is part of the body’s normal defense system. If you form inhibitors, it may stop ADVATE from working properly. Consult with your healthcare provider to make sure you are carefully monitored with blood tests for the development of inhibitors to factor VIII.

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

The risk information provided here is not comprehensive. To learn more, talk with your health care provider or pharmacist about ADVATE. The FDA approved product labeling can be found at www.ADDvate.com or 1-888-4-ADVATE.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1–800-FDA-1088.

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Baxter
Bring it and be ready to infuse
XYNTHA SOLOFUSE brings together proven efficacy and all-in-one reconstitution—in a travel-anywhere kit.

Visit FreeTrialXyntha.com and see if you're eligible to get a one-time, 1-month supply up to 20,000 IU at no cost.*

What is XYNTHA?
XYNTHA® Antihemophilic Factor (Recombinant) is indicated in adults and children for the control and prevention of bleeding episodes in patients with hemophilia A (congenital factor VIII deficiency or classic hemophilia) and for the prevention of bleeding during surgery in patients with hemophilia A.

XYNTHA does not contain von Willebrand factor and, therefore, is not indicated for von Willebrand’s disease.

Important Safety Information for XYNTHA

- Call your healthcare provider or go to the emergency department right away if you have any of the following symptoms because these may be signs of a serious allergic reaction: wheezing, difficulty breathing, chest tightness, turning blue (look at lips and gums), fast heartbeat, swelling of the face, faintness, rash, low blood pressure, or hives.
- XYNTHA contains trace amounts of hamster protein. You may develop an allergic reaction to these proteins. Tell your healthcare provider if you have had an allergic reaction to hamster protein.
- Call your healthcare provider right away if bleeding is not controlled after using XYNTHA; this may be a sign of an inhibitor, an antibody that may stop XYNTHA from working properly. Your healthcare provider may need to take blood tests to monitor for inhibitors.
- Across all clinical studies, the most common side effects (10% or more) with XYNTHA in adult and pediatric previously treated patients (PTPs) were headache (25% of subjects), joint pain (25%), fever (21%), and cough (11%). Other side effects reported in 5% or more of patients were: diarrhea, vomiting, weakness, and nausea.
- XYNTHA is an injectable medicine administered by intravenous (IV) infusion. You may experience local irritation when infusing XYNTHA after reconstitution in XYNTHA® SOLOFUSE®.

Please see brief summary of full Prescribing Information for XYNTHA and XYNTHA SOLOFUSE on the next page.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

*You must be currently covered by a private (commercial) insurance plan. If you are not eligible for the trial prescription program, you may find help accessing Pfizer medicines by contacting Pfizer's RxPathways program. For questions about the XYNTHA Trial Prescription Program, please call 1-800-710-1379 or write us at XYNTHA Trial Prescription Program administrator, MedVantx, PO Box 5736, Sioux Falls, SD 57117-5736.

*This card will be accepted only at participating pharmacies. This card is not health insurance. No membership fee.

Need help accessing Pfizer medicines?
Pfizer’s RxPathways program may be able to help. Call 1-888-327-7787 or visit www.PfizerRxPath.com.

Pfizer RxPathways is a joint program of Pfizer Inc and the Pfizer Patient Assistance Foundation™.
**Brief Summary**

See package insert for full Prescribing Information, including patient labeling. For further product information and current patient labeling, please visit XYNTHA.com or call Pfizer Inc toll-free at 1-800-679-3477.

Please read this Patient Information carefully before using XYNTHA and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your healthcare provider about your medical problems or your treatment.

**What is XYNTHA?**

XYNTHA is an injectable medicine that is used to help control and prevent bleeding in people with hemophilia A. Hemophilia A is also called classic hemophilia. Your healthcare provider may give you XYNTHA when you have surgery.

XYNTHA is not used to treat von Willebrand's disease.

**What should I tell my healthcare provider before using XYNTHA?**

Tell your healthcare provider about all your medical conditions, including if you:

- have any allergies, including allergies to hamsters.
- are pregnant or planning to become pregnant. It is not known if XYNTHA may harm your unborn baby.
- are breastfeeding. It is not known if XYNTHA passes into your milk and if it can harm your baby.

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

**How should I infuse XYNTHA?**

Step-by-step instructions for infusing with XYNTHA are provided at the end of the complete Patient Information leaflet. The steps listed below are general guidelines for using XYNTHA. Always follow any specific instructions from your healthcare provider. If you are unsure of the procedures, please call your healthcare provider before using.

**Call your healthcare provider right away if bleeding is not controlled after using XYNTHA.** Your body can also make antibodies against XYNTHA (called "inhibitors") that may stop XYNTHA from working properly. Your healthcare provider may need to take blood tests from time to time to monitor for inhibitors.

Call your healthcare provider right away if you take more than the dose you should take.

Talk to your healthcare provider before traveling. Plan to bring enough XYNTHA for your treatment during this time.

**What are the possible side effects of XYNTHA?**

Call your healthcare provider or go to the emergency department right away if you have any of the following symptoms because these may be signs of a serious allergic reaction:

- wheezing
- difficulty breathing
- chest tightness
- turning blue (look at lips and gums)
- fast heartbeat
- swelling of the face
- faintness
- rash
- hives

Common side effects of XYNTHA are

- headache
- fever
- nausea
- vomiting
- diarrhea
- weakness

Talk to your healthcare provider about any side effect that bothers you or that does not go away. You may report side effects to FDA at 1-800-FDA-1088.

**How should I store XYNTHA?**

Do not freeze.

Protect from light.

**XYNTHA Warnings**

Store XYNTHA in the refrigerator at 36° to 46°F (2° to 8°C). Store the diluent syringe at 36° to 77°F (2° to 25°C).

XYNTHA can last at room temperature (below 77°F) for up to 3 months. If you store XYNTHA at room temperature, carefully write down the date you put XYNTHA at room temperature, so you will know when to either put it back in the refrigerator, use it immediately, or throw it away. There is a space on the carton for you to write the date.

If stored at room temperature, XYNTHA can be returned one time to the refrigerator until the expiration date. Do not store at room temperature and return it to the refrigerator more than once. Throw away any unused XYNTHA after the expiration date.

Infuse XYNTHA within 3 hours of reconstitution. You can keep the reconstituted solution at room temperature before infusion, but if you have not used it within 3 hours, throw it away. Do not use reconstituted XYNTHA if it is not clear to slightly opalescent and colorless.

Dispose of all materials, whether reconstituted or not, in an appropriate medical waste container.

**XYNTHA SOLOFUSE**

Store in the refrigerator at 36° to 46°F (2° to 8°C).

XYNTHA SOLOFUSE can last at room temperature (below 77°F) for up to 3 months. If you store XYNTHA SOLOFUSE at room temperature, carefully write down the date you put XYNTHA SOLOFUSE at room temperature, so you will know when to throw it away. There is a space on the carton for you to write the date.

Throw away any unused XYNTHA SOLOFUSE after the expiration date.

Infuse within 3 hours after reconstitution or after removal of the grey rubber tip cap from the prefilled dual-chamber syringe. You can keep the reconstituted solution at room temperature before infusion, but if it is not used in 3 hours, throw it away.

Do not use reconstituted XYNTHA if it is not clear to slightly opalescent and colorless.

Dispose of all materials, whether reconstituted or not, in an appropriate medical waste container.

**What else should I know about XYNTHA?**

Medicines are sometimes prescribed for purposes other than those listed here. Talk to your healthcare provider if you have any concerns. You can ask your healthcare provider for information about XYNTHA that was written for healthcare professionals.

Do not share XYNTHA with other people, even if they have the same symptoms that you have.

This brief summary is based on the Xyntha® (Antihemophilic Factor [Recombinant]) Prescribing Information LAB-0616-lO, revised 10/14, and LAB-0505-90, revised 10/14.
THE FIRST AND ONLY FACTOR VIII WITH A PROLONGED HALF-LIFE

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

Meet your CoRe Manager Lisa Schmitt
E: lisa.schmitt@biogen.com  T: 978-407-7713
This information is not intended to replace discussions with your healthcare provider.

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: control and prevention of bleeding episodes, perioperative management (surgical prophylaxis), and routine prophylaxis to prevent or 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.
Common side effects of ELOCTATE are joint 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.
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?

Common side effects of ELOCTATE are joint pain and general discomfort.

Allergic reactions may occur. 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, which may stop ELOCTATE from working properly. Your healthcare provider may give you blood tests to check for inhibitors.

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.

Manufactured by:
Biogen Idec Inc.
14 Cambridge Center, Cambridge, MA 02142 USA
U.S. License # 1697

44279-01

ELOCTATE™ is a trademark of Biogen Idec.

Issued June 2014
Indications and Usage
NovoEight® (Antithrombin Factor (Recombinant)) is indicated for use in adults and children with hemophilia A for control and prevention of bleeding, perioperative management, and routine prophylaxis to prevent or reduce the frequency of bleeding episodes.
NovoEight® is not indicated for the treatment of von Willebrand disease.

Important Safety Information
Do not use in patients who have had life-threatening hypersensitivity reactions, including anaphylaxis, to NovoEight® or its components, including hamster proteins.
Administration of NovoEight® in patients who have had previous life-threatening reactions to the recombinant product should be done under medical supervision.

ADVERSE REACTIONS:
The most frequently reported adverse reactions (≥ 0.5%) were injection site reactions, increased hepatic enzymes, and pyrexia.

Clinical Trials Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in clinical trials of another drug and may not reflect the rates observed in clinical practice.

RELIABILITY
0 INHIBITORS CONFIRMED
One of the largest clinical trials with no inhibitors confirmed in 213 FDA

PURITY
20 NM FILTERS
Impurities levels determined by double-reversed phase high-performance liquid chromatography

PORTABILITY
86°F for 12 HOURS
Higher storage temperature for the longest duration

Manufactured by:
Novo Nordisk A/S
Novo Allé, DK-2880 Bagsvaerd
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More Detailed Information is available upon request.
For more information contact:
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800 Scudders Mill Road
Plainsboro, NJ 08536
USA
1-844-30-EIGHT
Manufactured by:
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Novo Allé, DK-2880 Bagsvaerd
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Novo Eight® Anthrombic Factor
(Recombinant)

Antithrombin Factor
(Recombinant)
Mission Statement
The New England Hemophilia Association is a non-profit organization dedicated to improving the quality of life for persons with bleeding disorders and their families through education, support, and advocacy.

Services include:
- Information and referral
- Medical symposia and educational programs
- Social and recreational activities for children and families
- Family Camp
- Teen Programs
- Spanish-language programming
- Peer support groups
- Emergency financial assistance
- Advocacy and Legislative Support

Please contact the office for more information

Phone: (781) 326-7645
E-mail: info@newenglandhemophilia.org
Website: www.newenglandhemophilia.org