LIVING FIT WITH VON WILLEBRAND DISEASE

This piece was originally published by the Hemophilia Federation of America (HFA) in May of 2015. We are re-publishing with permission from HFA.

One of the most common bleeding disorders in women is von Willebrand Disease (vWD), which occurs in about 1% of the US population. Heavy bleeding is one of the most common problems women report to their doctors. It affects more than 10 million American women each year. This means that about one out of every five women has heavy menstrual bleeding. Women often live with...
HIT THE GROUND RUNNING!

Saturday, September 12, 2015

Location: North Park/Harmar Grove Shelter
Allison Park, PA
Registration: 7:30am
Race Start Time: 8:30am
Race Distance: 5K

An expected 150+ Western Pennsylvanians will hit the ground running to raise money for the Western Pennsylvania Chapter of the National Hemophilia Foundation in the 6th Annual Run For Their Lives 5K!

WPCNHF has once again partnered with Elite Runners! Register today at www.wpcnhf.org/event/run

COME FOR THE RUN AND STAY FOR THE FUN!

Registration: 9:00am
Walk Start Time: 10:00am
Walk Distance: 5K

Join us for the 7th Annual Western Pennsylvania Hemophilia Walk! We will walk to raise critical FUNDS and AWARENESS for the bleeding disorders community. The event will include entertainment for the entire family. All proceeds stay local to benefit WPCNHF! Register your team today!

For more information, please visit, www.hemophilia.org/walk and click on PA or contact Kara Dornish, Marketing and Events Manager, by phone 724-741-6160 or email kara@wpcnhf.org.
Dear Chapter Members and Stakeholders,

Summer is here! While summer activities are just beginning, the chapter has been hard at work developing programs and advocating for our members. Already in 2015, we had infusion day, a very successful teen retreat, and programming for men and women. Our annual Harrisburg Days advocacy trip produced some good results and relationships with newer legislators and it was great to see new faces at the event this year!

You know it is summer when we start talking about Camp! Camp Hot-to-Clot was a success and I want to thank all that participated in making that a success – a big shout out to the camp Planning Committee who, along with all of the volunteers, did a wonderful job!

As we begin our summers, please remember to mark your calendars for the Annual Meeting on July 23rd in Homestead. If you have not done so already, be sure to register your team for the Annual Hemophilia Walk and encourage your family and friends to take part in the Walk as well as Run for Their Lives*, both on September 12, 2015. These events continue to be among our most important fundraisers that allow us to provide the programming and services our members want and need as we implement our new mission and strategic plan.

As always, I want to THANK YOU for your continued support of the Chapter and remind you that you are free to contact us if we can be of service or if you need assistance. I look forward to seeing you all at the Annual Meeting!

Sincerely,

Scott E. Miller, CPA, J.D., DBA
WPCNHF Board President

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Amish Outreach

As part of the Chapter’s dedication to bring programs to more communities in our region, we have begun to offer a series of educational programs, exclusively for Amish members. Our first stop was Punxsutawney, in April, and due to popular demand, we will be returning this summer! The first topic we offered was Hemophilia Basics, which was presented by Nayan Heath, a nurse educator, with Pfizer, Inc. In the fall, we will expand our program into other Amish communities, as well as offer additional topics.
Calendar of Upcoming Events

Wednesday, July 15
Hemophilia Overview – Amish Only
Punxsutawney, PA

Thursday, July 23
WPCNHF Annual Meeting
Plus Exhibit Displays
Homestead, PA

Saturday, August 1
Program for Female Caregivers
Pittsburgh, PA

Thursday, August 13 – Saturday, August 15
NHF Annual Meeting
Dallas, TX

Saturday, August 29
Cracking the Code and Power of Empowerment
Plus Exhibit Displays
Erie, PA

Saturday, August 29
Waldameer Park
Erie, PA

Saturday, September 12
Hemophilia Walk
North Park, Allison Park, PA

Saturday, September 12
Run For Their Lives 5K™
North Park, Allison Park, PA

Saturday, October 24
Self-Advocacy
Plus Exhibit Displays
Ligonier, PA

Friday, November 20 – Sunday, November 22
Take A Bough™
Pittsburgh, PA

Saturday, December 5
Winterfest
Wheeling, WV

Combined Federal Campaign
WPCNHF is an approved charitable organization for the Combined Federal Campaign (CFC). If you participate in the CFC, please consider designating all or a portion of your donation to the Chapter.

WPCNHF CFC Number is: 81343

Visit IXFINITY.com for more information.

Call your IXperience Concierge™ at 1-855-IXINITY (1-855-494-6489).

Ask us about sponsorship opportunities and how you can help!
ADVATE HAS A PROVEN SAFETY PROFILE1-7

Low risk of inhibitor development in previously treated patients (PTPs) demonstrated in clinical studies1-3

- 1 low-titer, nonpersistent inhibitor (<1%) in a pivotal study4† (n=108)
- 0 inhibitors in a continuation study15 (n=82); a pediatric study15 (n=53); a surgery study5‡ (n=59); a Japanese study7 (n=15); and a prophylaxis study8† (n=73)

Patients with an estimated ≥150 factor VIII exposure days1,3,4
Some patients participated in more than 1 study.2
Patients with an estimated ≥50 factor VIII exposure days3

There was 1 case of a possible low-titer factor VIII inhibitor, which was unconfirmed, unaccompanied by symptoms of inhibitor presence, and disappeared at the subject’s subsequent test.1

(95% confidence interval, 0.02%–2.13%)

6 CLINICAL STUDIES / 270 PATIENTS WITH MODERATELY SEVERE TO SEVERE HEMOPHILIA A

ADVATE [Antihemophilic Factor (Recombinant)] Important Information

Indications

ADVATE is a medicine used to replace clotting factor (factor VIII or antihemophilic factor) that is missing in people with hemophilia A (also called “classic” hemophilia).

ADVATE is used to prevent and control bleeding in adults and children (0-16 years) with hemophilia A. Your healthcare provider may give you ADVATE when you have surgery. ADVATE can reduce the number of bleeding episodes in adults and children (0-16 years) when used regularly (prophylaxis).

ADVATE is not used to treat von Willebrand disease.

DETAILED IMPORTANT RISK INFORMATION

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

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

You should tell your healthcare provider if you:
- Have or have had any medical problems.
- Take any medicines, including prescription and non-prescription medicines, such as over-the-counter medicines, supplements or herbal remedies.
- Have any allergies, including allergies to mice or hamsters.
- Have been told that you have inhibitors to factor VIII (because ADVATE may not work for you).

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

You can have an allergic reaction to ADVATE.

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

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

Tell your healthcare provider about any side effects that bother you or do not go away or if your bleeding does not stop after taking ADVATE.

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


Baxter and Advate are trademarks of Baxter International Inc. USBS/34/15-0032
ADVATE [Antithrombotic Factor (Recombinant)]

Lyophilized Powder for Reconstitution for Intravenous Injection

**Brief Summary of Prescribing Information:** Please see package insert for full Prescribing Information.

### INDICATIONS AND USAGE

ADVATE [Antithrombotic Factor (Recombinant)] is a recombinant antithrombotic factor indicated for use in children and adults with hemophilia A (congenital factor VIII deficiency or classic hemophilia) for:

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

ADVATE is not indicated for the treatment of von Willebrand disease.

### CONTRAINDICATIONS

ADVATE is contraindicated in patients who have life-threatening hyperallergic reactions, including anaphylaxis, to mouse or hamster protein or other constituents of the product (mannitol, trehalose, sodium chloride, hedimine, tris, calcium chloride, polysorbate 80, and/or glutathione).

### WARNINGS AND PRECAUTIONS

#### Hypersensitivity Reactions

Allergic-type hypersensitivity reactions, including anaphylaxis, have been reported with ADVATE. Symptoms include dizziness, paresthesia, rash, flushing, facial swelling, urticaria, dyspnea, and pruritus.

ADVATE contains trace amounts of mouse immunoglobulin G (Mr/G) <0.1 ng/μg ADVATE, and hamster proteins ≤0.5 ng/μg ADVATE. Patients treated with this product may develop hypersensitivity to these non-human mammalian proteins.

Discontinue ADVATE if hypersensitivity symptoms occur and administer appropriate emergency treatment.

### Neutralizing Antibodies

Neutralizing antibodies (inhibitors) have been reported following administration of ADVATE predominantly in previously untreated patients (PUPs) and previously minimally treated patients (MTPs). Monitor all patients for the development of factor VIII inhibitors by appropriate clinical observation and laboratory testing. If expected plasma factor VIII activity levels are not attained, or if bleeding is not controlled with an expected dose, perform an assay that measures factor VIII inhibitor concentration. [see Warnings and Precautions]

### Monitoring Laboratory Tests

- Monitor plasma factor VIII activity levels by the one-stage clotting assay to confirm the adequate factor VIII level has been achieved and maintained when clinically indicated. [see Dosage and Administration]
- Perform the Bethesda assay to determine if factor VIII inhibitor is present. If expected factor VIII activity plasma levels are not attained, or if bleeding is not controlled with the expected dose of ADVATE, use Bethesda Units (BU) to titr inhibitors.
  - If the inhibitor titer is less than 10 BU per mL, the administration of additional antihemophilic factor concentrate may neutralize the inhibitor and may permit an appropriate hemostatic response.
  - If the inhibitor titer is above 10 BU per mL, adequate hemostasis may not be achieved. The inhibitor titer may rise following ADVATE infusion as a result of an anamnestic response to factor VIII. The treatment or prevention of bleeding in such patients requires the use of alternative therapeutic approaches and agents.

### ADVERSE REACTIONS

The serious adverse reactions seen with ADVATE are hypersensitivity reactions and the development of high-titer inhibitors necessitating alternative treatments to factor VIII.

The most common adverse reactions observed in clinical trials (frequency ≥10% of subjects) were pyrexia, headache, cough, nasopharyngitis, vomiting, arthralgia, and limb injury.

#### Clinical Trial 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.

ADVATE has been evaluated in five completed clinical trials in previously treated patients (PTPs) and one ongoing trial in previously untreated patients (PUPs) with severe to moderately severe hemophilia A (factor VIII ≤2% of normal). A total of 234 subjects have been treated with ADVATE as of March 2006. Total exposure to ADVATE was 44,906 infusions. The median duration of participation per subject was 370.5 days (range: 1 to 1,236) days and the median number of exposure days to ADVATE per subject was 128 (range: 1 to 598).

The summary of adverse reactions with a frequency ≥5% (defined as adverse events occurring within 24 hours of infusion or any adverse event causally related occurring within the trial period) is shown in Table 3.

No subject was withdrawn from a clinical trial due to an adverse reaction. There were no deaths in any of the clinical trials.

### Summary of Adverse Reactions with a Frequency ≥5% (N = 234 Treated Subjects)

<table>
<thead>
<tr>
<th>MedDRA® System Organ Class</th>
<th>MedDRA® Preferred Term</th>
<th>Number of ADRs</th>
<th>Number of Subjects</th>
<th>Percent of Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>General disorders and administration site conditions</td>
<td>Pyrexia</td>
<td>78</td>
<td>50</td>
<td>21</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>Headache</td>
<td>104</td>
<td>49</td>
<td>21</td>
</tr>
<tr>
<td>Respiratory, thoracic, and mediastinal disorders</td>
<td>Cough</td>
<td>75</td>
<td>44</td>
<td>19</td>
</tr>
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<td>Infections and infestations</td>
<td>Nasopharyngitis</td>
<td>61</td>
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<td>Musculoskeletal and connective tissue disorders</td>
<td>Arthralgia</td>
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<td>12</td>
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<td>Limb injury</td>
<td>55</td>
<td>24</td>
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### Precautions

- If the inhibitor titer is above 10 BU per mL, adequate hemostasis may not be achieved. The inhibitor titer may rise following ADVATE infusion as a result of an anamnestic response to factor VIII. The treatment or prevention of bleeding in such patients requires the use of alternative therapeutic approaches and agents.

### Dosage and Administration

- Perform the Bethesda assay to determine if factor VIII inhibitor is present. If expected factor VIII activity plasma levels are not attained, or if bleeding is not controlled with the expected dose of ADVATE, use Bethesda Units (BU) to titr inhibitors.
  - If the inhibitor titer is less than 10 BU per mL, the administration of additional antihemophilic factor concentrate may neutralize the inhibitor and may permit an appropriate hemostatic response.
  - If the inhibitor titer is above 10 BU per mL, adequate hemostasis may not be achieved. The inhibitor titer may rise following ADVATE infusion as a result of an anamnestic response to factor VIII. The treatment or prevention of bleeding in such patients requires the use of alternative therapeutic approaches and agents.

### Immunogenicity

The development of factor VIII inhibitors with the use of ADVATE was evaluated in clinical trials with pediatric patients (<5 years of age) and adults. The treatment of factor VIII inhibitors requires the use of alternative therapeutic approaches and agents.

## Post-Marketing Experience

The following adverse reactions have been identified during post-approval use of ADVATE. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Among patients treated with ADVATE, cases of serious allergic/hypersensitivity reactions including anaphylaxis have been reported and factor VIII inhibitor formation (observed predominantly in PUPs). Table 4 represents the most frequently reported post-marketing adverse reactions as MedDRA Preferred Terms.

### Summary of Adverse Reactions with a Frequency ≥5% (N = 234 Treated Subjects)

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*These reactions have been manifested by dizziness, paresthesia, rash, flushing, face swelling, urticaria, and/or pruritus.

Living Fit With Von Willebrand Disease

(Continued from page 1)

their symptoms without a diagnosis until a major bleeding event occurs. Lisa describes how a routine tonsillectomy almost cost her life and how she eventually found her way to a diagnosis. Here is Lisa’s story:

I was very healthy, active and in great shape when I went in for a routine tonsillectomy during my college years. I never expected this simple procedure to end up a life or death battle. I had the surgery about ten days before Christmas because I had been suffering from a lot of pain in my ears. On Christmas day, I started to bleed. I had my throat cauterized and was sent home. I started to hemorrhage again and this time almost didn’t make it to the hospital. I almost bled – out on the way to the emergency room. The ENT specialist ended up working on me all night long to try and save my life. If only I had been diagnosed early on in my life, my bleeding episodes could have been reduced.

At the time of my surgery, the doctors and specialists didn’t know how to really explore why I had so many bleeding episodes. I hemorrhaged about twelve to fifteen times. I would bleed every twelve to twenty-four hours just like clockwork.

Eleven years later, when I had better health insurance, I had more extensive blood tests and was finally diagnosed with VWD type 1. Thankfully now I knew what I was dealing with and learned how to live with it. The hard part was over, now it was how to adapt my life accordingly. I know that I am not the only women who has been diagnosed later in life, there are so many other women out there like my situation.

Despite my bleeding disorder, I have always loved and excelled in sports. During junior high school I competed in archery and was advised to train and try out for the Olympics. Due to lack of finances I never made it to the next level so I looked at sports that didn’t cost so much and earned my green belt in Shorin – Ryu karate. During my college years I eventually made it to first degree black belt. I had suffered from internal bleeding after my green belt test after getting kicked really hard in the ribs. I coughed up some blood for about a week after and then was ok. I then became interested and started weight training and bodybuilding with the goal of competing. Many weightlifters encouraged me to compete in powerlifting – but I favored bodybuilding. I trained hard and joined a team of competitors called Body Armor.

I started the hardcore fitness regime of bodybuilding style training and fitness dieting. The results were amazing! I got into even better shape and was able to do four National Physique Committee (NPC) shows. It was hard to believe that I had once survived a life threatening bleeding episode and didn’t think I’d ever leave the hospital alive! I was now an NPC level athlete with a long way to go. I won a sword for 4th place which has become part of my business logo.

I’m a firm believer in getting into some level of fitness and maintaining it depends on your diagnosis, age and ability. My goal is to motivate others with bleeding disorders to get into better shape. It’s even more important for those with health challenges to get into shape. It can help you look and feel better. I have written for both fitness and fashion magazines with the idea of using my own background as an example to others who may have the same or similar experiences or issues. I am also a survivor of stage 1 breast cancer in 2008. I continued to maintain my healthy lifestyle and trained throughout radiation treatment. I am here as proof that there is life after illness!

Lisa N. resides in Pennsylvania. She holds a BA in Psychology. She writes a blog on her website: www.fitsurvivor.com and has tried out for the American Gladiators television show.

Bowling Marathon to Benefit WPCNHF

The Western Pennsylvania Chapter of the National Hemophilia Foundation Strikes Out Bleeding Disorders

Starting on April 1, 2015 our Bowling for Bleeding Disorders fundraising campaign began. It ended on May 3rd with WPCNHF’s 3rd Annual Bowling for Bleeding Disorders bowling marathon.

Bowling for Bleeding Disorders was once again held at Paradise Island Bowl in Neville Township, Pennsylvania. This year, 11 teams bowled for three hours. The cost to bowl was $25 per participant which included shoe rental, bowling, pizza, wings, and unlimited soft drinks.

Trophies were given out during the event to the highest scoring and lowest scoring bowler and team and also to the highest fundraising team. The highest fundraising team award went to Gino’s Gutter Gang! Way to go!

Nearly 60 people attended the event. The sponsors of the event included Baxter, The Hemophilia Center of Western Pennsylvania, Bayer, Cottrill’s Specialty Pharmacy, Novo Nordisk, Octapharma, and Pfizer. Over $17,000 was raised to benefit the Western Pennsylvania Chapter of the National Hemophilia Foundation.

WPCNHF would like to thank all who attended and participated in making the 3rd Annual Bowling for Bleeding Disorders the most successful one yet!
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.

FREE TRIAL—Get In and Get It

Get a one-time, 1-month supply up to 20,000 IU at no cost to you—talk to your health care provider to see if XYNTHA® SOLOFUSE® is right for you. For first-time use by commercially insured patients only. Terms and conditions apply.

See FreeTrialXyntha.com—or scan the QR code.

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

- Across all clinical studies, the most common side effects (10% or more) with XYNTHA in adult and pediatric previously treated patients (PTPs) were headache (26% 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®.

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

Terms and conditions apply.*
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 1-800-879-3477.

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.

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.

Tell 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 Vials

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

XYNTHA SOLOFUSE

Store in the refrigerator at 36°F to 46°F (2°C 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-0516-5.0, revised 10/14, and LAB-0500-9.0, revised 10/14.
The Hemophilia Center of Western Pennsylvania clotting factor program was established in 2000 as a complement to the Center’s other comprehensive care services. The clotting factor program allows the Center the opportunity to offer clotting factor to its patients, thereby supplementing its comprehensive treatment care model and providing the best possible care for its patients.

Please contact the Center at (412) 209-7280 for more information about how this program can benefit you and the entire bleeding disorder community.

The Hemophilia Center of Western Pennsylvania supports patient choice consistent with the Veterans Health Care Act of 1992 and maintains a freedom of choice policy where patients are informed of their choices regarding factor replacement products.

Factor Program Services
- All factor product brands available
- Online factor ordering available
- 24 – 48 hour delivery
- Same day courier service for emergent needs
- On-call services, 24/7
- Home treatment supplies
- Lot tracking for recall notification
- Online home treatment records
- Insurance benefit information assistance

Patient Benefits
- Direct communication and service from the Center’s treatment team
- Support of the Center’s operations
- Expansion of patient services

Harrisburg Day
By Katie Berry

It was Monday morning, and I had to get up early - very early - but not for school. My brothers, father, and I were going to the state capitol, Harrisburg, to talk with people in the government about money for research into bleeding disorders. It was April 20th, and it was early.

We drove to Harrisburg from Erie because we felt it was important to volunteer and help get the message out about bleeding disorder programs and services. Several people in my family have bleeding disorders, and these programs are important to them and to people like us. And my dad said it would be a good lesson in how our government works.

After a short discussion on our message, we were split into groups, given handouts to give to our senators and representatives, and given visit schedules. We then went to meetings in the Capitol with the senators and representatives to talk about funding our programs. My dad and another man on our team, Dr. Miller, did most of the talking, but I felt I was helping just by being there. I could tell it was important that the senators and representatives see the people like me who need their help. The senators and representatives were very nice, listened to our stories and to our requests, and promised their support when the state makes its budget.

I’m glad to have helped. It was a very long day, but I feel we made a difference not just for me, but for others with bleeding disorders, too. Although next time, I’d like to get up later!

Happy Summer from the HCWP

We hope all of you are enjoying the weather. We have had a busy few months between our outreach clinics and camp. Some recent excitement at the Center included a twinning visit with Dr. James Rwehebura from our Tanzanian partner, Muhimbili National Hospital. Our staff had a reciprocal opportunity to discuss, listen, and learn with Dr. Rwehebura regarding treatment, care, and resources. Also at the Center, our genetic counselor, Michelle Alabek will have a student shadowing her for the summer. Her name is Megan Ensinger. She is in her second year of her Masters in Genetic Counseling degree at University of North Carolina – Greensboro. Another wonderful announcement is our new clinic manager, Deborah J. Solvay, MSN, RN, CCRN. Deborah brings over 15 years of management experience to the Center.

As the summer moves along, please remember that in addition to packing for your summer vacation, contact us to request a travel letter, whether you are flying or driving, about two weeks prior to your trip to ensure timing for doctor review and signature. It is also a good time to check your medical ID jewelry. Is it current? Are you wearing it? Wearing medical ID jewelry gives a voice to you/your child when unable to speak in an emergency circumstance. Call the Center if you need to update or get one. An additional summer reminder for the kiddos (and adults, alike), please wear your helmet. The Center has helmets available on site. Please ask when you are in the office so that we can provide your child with one.

The Hemophilia Center of Western Pennsylvania

The Hemophilia Center of Western Pennsylvania clotting factor program was established in 2000 as a complement to the Center’s other comprehensive care services. The clotting factor program allows the Center the opportunity to offer clotting factor to its patients, thereby supplementing its comprehensive treatment care model and providing the best possible care for its patients.

The Hemophilia Center of Western Pennsylvania supports patient choice consistent with the Veterans Health Care Act of 1992 and maintains a freedom of choice policy where patients are informed of their choices regarding factor replacement products.
Spotlight on the Member: Johnson-Huber Family

Delores Johnson-Huber, a Certified Nurse Assistant, lives in Clairton, PA, with her two children. Her son Ethan, age 8, and her newborn son, Kyrie, both have severe Hemophilia A. Like many other parents who have multiple children, Delores can already feel the difference between being a first-time parent and one with experience behind her, and she has a great sense of humor about the differences (calling to mind a recent diaper commercial that depicts that very thing)! In addition to parenting experience, having knowledge about hemophilia and experience caring for a child with hemophilia has helped make that aspect of parenting go more smoothly the second time around. In addition, Delores has been diagnosed with von Willebrand disease and was treated with factor following the birth of her second child. She said it has made a huge difference in her recovery from childbirth.

When her first child was born, Delores didn’t know he had a bleeding disorder until after he was circumcised and the bleeding wouldn’t stop. Ethan was tested and then treated with factor to control the bleed. This time, Delores was tested during pregnancy and found out that her second son had hemophilia before he was born. Kyrie was given factor before the procedure and didn’t have any complications.

Ethan’s first year was pretty uneventful, as far as bleeds were concerned (with the exception of his circumcision). However, he began to have frequent nose bleeds and needed to be treated accordingly. Due to his frequent infusions, he had a port implanted when he was approximately 18 months old. To control his bleeds, he required factor at least three times a week and sometimes up to twice a day. His port remained in him for several years. Unfortunately, he had numerous port infections and was hospitalized for months at a time, spending the better part of his toddler years in the hospital. The port was removed when he was almost four years old and since then factor has been infused through a vein in his arm.

When Ethan was about 4 ½ years old, he entered a study for a longer-lasting factor and he no longer had frequent nose bleeds. As a result, Ethan was able to be more active and participate in activities most kids his age did. When he was old enough, Ethan went to school. Unfortunately, Delores was called to the school frequently regarding concern over potential bleeds. Last year, she moved to a new school district and the change has been positive for everyone. The school nurse is a former nurse from Children’s Hospital and she is quite comfortable assessing bleeds. Ethan adjusted quickly to his new school; he just finished the third grade and is an honor student!

This past year, Ethan played on a baseball team for the first time! He’s the catcher for his team and is doing a great job! His coach obtained protective equipment, specifically to help him prevent bleeds or injury. As a bonus, all of the activity has helped him shed about 15 pounds and has him feeling more energetic. Delores also noted that his factor dose was adjusted for the weight loss. She enjoys spending time at the field, watching Ethan play baseball.

Last summer, Ethan attended Camp Hot-to-Clot for the first time. While at camp, he self-infused for the first time and has been self-infusing ever since! He attended Camp Hot-to-Clot again this year and also attended Camp Hemovon for the first time. The family has been active with the Chapter the last few years and has attended a number of educational and social events. Ethan has enjoyed attending a Pittsburgh Riverhounds soccer game, Pittsburgh Pirates Baseball game, and the Winterfest at Dave & Busters. He looks forward to seeing friends he made at camp and other programs at these events. Delores and Ethan also attended the NHF Annual Meeting in Washington, D.C. with the Chapter last fall.

Delores and Ethan are more than willing to share their stories and experiences with others in the community. In fact, when Ethan was only four years old, he was asked to talk with some children with ports who were his age or younger about having his port removed and receiving his treatments through a vein in his arm instead. A tip that Delores likes to share with other families who are beginning home infusion is to make a special song playlist or have a special video that your child is only allowed to play during the infusion process. She found that these things helped her child to relax and stay still during infusions.

Food & Fitness Basics

(Continued from page 1)

Directions:
In a small mixing bowl, combine shallots, garlic, honey, and ¼ cup Aprihop together
1. In a small saucepan, combine sugar, ¼ cup of sliced apricots, and 1 cup Aprihop beer to a medium simmer,
allow this to reduce down to about half-way. The consistency should be thicker, yet still loose like a jelly.
2. Add the apricot mixture to the mixing bowl and combine.
3. Whisk in the oil to create an emulsification.
4. Adjust the seasoning with salt.
5. Toss with arugula enough just to coat.
6. Garnish salad with goat cheese, thin slices of dried apricots and slivered almonds. Scoop into endive leaves if desired.

Tips:
Honey helps keep foods from getting bitter, when cooking with beer. Arugula is a peppery flavored lettuce that goes well with sweet dressings.
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:
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14 Cambridge Center, Cambridge, MA 02142 USA
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Camp Hot-to-Clot

Time travel was the theme this year and we sure had a lot of fun with it! Camp Hot-to-Clot, which was held from Sunday, June 7 – Saturday, June 13, at Camp Kon-O-Kwee, in Fombell, PA, started a day early for our Leaders-in-Training (LITs). The LITs (select campers who applied, interviewed, and were chosen for the Leaders-in-Training program) attended training on Saturday and helped get things ready for camp. Sunday morning they constructed a time machine and then attended additional training sessions with camp counselors. At four o’clock, the campers arrived and we were off to a full week of activities!

Each day during breakfast and dinner, someone would enter the time machine and bring back people from other eras. The campers enjoyed some very entertaining skits and also learned about the history of bleeding disorders in the process. Along the way, we met Queen Victoria, Grigori Rasputin, Alexei and his parents Empress Alexandra Feodorovna and Emperor Nicholas II of Russia, a knight from medieval times, cowboys from the wild west, Dr. Erik von Willebrand, Dr. Judith Graham Pool… you never knew who was going to come out of the time machine next!

Throughout the week, campers had the opportunity to participate in the many activities that Camp Kon-o-Kwee has to offer, including boating, fishing, archery, BB range, disc golf, soccer, gaga, volleyball, swimming, dancing, drama, arts & crafts, yoga, deck hockey, basketball, splash pad, climbing wall, low ropes, high ropes, and zip line!

Theme-related activities were also incorporated throughout the week. The campers created individual time capsules to bury/store at home. In addition, one large time capsule for Camp Hot-to-Clot was assembled. What went into the Camp Hot-to-Clot time capsule? You’ll have to check back in 10 years, when the campers at Camp Hot-to-Clot 2025 open it! The campers enjoyed participating in a medieval tournament that included sword fighting, castle building, and jousting—Camp Hot-to-Clot style! The week also included a dance party, tie-dying camp T-shirts, and a movie with a time-travel theme.

In keeping with Camp Hot-to-Clot tradition, the campers participated in a service project to help give back. This year, they assembled personal hygiene kits to be distributed by Community Human Services to homeless people in Pittsburgh. And to help educate the public, the teenagers create a couple of “Public Service Announcements” (PSAs): one for school nurses and one for the general public regarding misconceptions about bleeding disorders. A link to the PSA on misconceptions can be found on the Chapter’s website.

During the week, there were also opportunities to learn more about bleeding disorders. In addition to the time travel skits, campers learned about self-infusion, treating bleeds, and about different types of bleeding disorders. A couple of brave young campers even self-infused for the first time and earned the Big Stick Award! Other campers, who don’t need to infuse, opted to learn the process in order to support their sibling or friend and earned the Stick Together Award!
From Baxter’s BioScience to Baxalta...

Baxter’s BioScience is expected to become Baxalta in mid-2015.

At Baxter’s BioScience, we see a world of endless possibilities for our patients. And although our name may be changing to Baxalta, our commitment to you is as strong as ever. At our foundation is an enduring heritage of innovation and advocacy. Your life is our inspiration to make a meaningful difference, so you can dream big, and experience life. We are excited about the future and hope you are too!