What summer camp means to a camper

One of our campers talks about KHF’s summer camp program:

My name is Mason Stout, and I have severe hemophilia A. I was asked to share with you why camp is important to me. Camp Discovery has allowed me to learn, discover, make friends, and have fun. It’s important to me and many others who attend because camp teaches us how to manage our bleeding disorder in an environment where we can have fun and meet others who face the same challenges.

When I could no longer use my port, which is a medical device implanted in my chest that my mother and doctors used to give me my medication, the learning experience I had at Camp Discovery prepared me to be responsible for this process on my own. Over the years at camp I had learned and practiced how to administer the injections of medication I have to take multiple times per week. When the port had to come out, I was ready to infuse my veins all on my own.

But it’s not all about learning how to self-infuse, and how to manage your bleeding disorder; it’s a place to go and meet with others like you, make friends, and have fun. Activities like capture the flag, zip-line, and swimming help me to get away from the stress of my bleeding disorder.

In a fun and welcoming environment camp has taught me and many others how to self-infuse and become more independent with their bleeding disorder. I am now interested in becoming a junior counselor so I can lead and teach others the same lessons I’ve learned. And that is why camp is so important to me and many others.

You have an opportunity to support summer camp with your donations throughout the year or by attending one of our special event fundraisers!

Mason’s testimonial is reprinted with permission from Matrix Health News, Spring 2012, a quarterly publication of Matrix Health Group, Spring 2012, Volume 7, Issue 2, Page 15

The Kentucky Hemophilia Foundation’s summer camp, aka “Camp Discovery,” is a five-day overnight program that is tailor-made to address the needs of children and youths that are struggling with the daily challenges of living with a chronic bleeding disorder. In addition to tried and true camp activities of canoeing, swimming, arts and crafts, and campfire sing-along’s, another set of all-time favorite activities have emerged such as Capturing the Flag game, zip lining, field trip, the Amazing Race game, and cultural enrichment night which acquaints campers with the culture, customs, food, language, and hemophilia care of another country.

Summer camp is focused on enjoying the outdoors, playing games, making friends, and having fun in a safe setting, but also on learning new skills and information. At the top of the list is campers’ desire to learn how to self-infuse. Thanks to our expert staff and on-site infirmary, from age 7 on campers learn the techniques of self-infusion step by step and the importance of maintaining good health. Their ultimate goal is to stick themselves so they can begin to master self-infusion.

Camp is definitely educational but in a fun package!
Antiviral Oral Combination Successfully Treats Certain HCV Patients

A clinical trial last month showed that a once daily, all-oral drug combination to treat chronic hepatitis C infection (HCV)—Bristol-Myers Squibb’s daclatasvir (NS5A replication complex inhibitor) and Gilead’s sofosbuvir (nucleotide NS5B inhibitor), direct-acting viral agents—was effective in all patients. It tested that drug combination with and without ribavirin, and excluded interferon, which is notorious for causing debilitating side effects. Results of the trial were presented by Mark Sulkowski, MD, professor of medicine at Johns Hopkins University during the 48th Annual Meeting of the European Association for the Study of the Liver (International Liver Congress 2013), April 24-28, 2013, in Amsterdam, The Netherlands.

All 41 study subjects had genotype 1 chronic HCV. More than 80% had subtype 1a, which is difficult to treat. They represented HCV patients who did not respond previously to interferon-based triple therapy using pegylated interferon and ribavirin, with an approved HCV protease inhibitor, either boceprevir (Victrelis) or telaprevir (Incivek).

Twelve weeks after the treatment ended, the rates of sustained viral response (SVR) were 100% in the sofosbuvir/daclatasvir arm and 95% in the sofosbuvir/daclatasvir/ribavirin arm. SVR indicates that a patient has “cleared” the virus for at least six months after completing therapy. It is achieved when viral levels drop to nearly undetectable levels.

Of the 21 patients who completed 24 weeks of follow-up once treatment ended, all had undetectable virus, or 100% SVR in both arms. Researchers reported that the drugs were well tolerated and there were few side effects.

“These data provide proof-of-concept that the combination of two potent direct-acting antivirals with different viral targets is effective in patients who failed pegylated interferon/ribavirin plus a protease inhibitor,” concluded Sulkowski. “We can tell our patients who failed triple therapy they now appear to have a path forward toward a cure.”

Source: AIDSmap.com, April 29, 2013; provided by the National Hemophilia Foundation
Hey All

Learning to self-infuse can be a challenge. Not that I have all the answers, but as a 58 year-old with severe hemophilia B who has been self-infusing for more than 40 years, I have lots of experience to share. I’m not saying I’m an expert and you should always seek your doctor’s opinion, but here are some tips that have helped me along the way:

1. Use the smallest needle possible. I use a 25-gauge butterfly needle for my infusions. I believe the smaller the needle, the less trauma and scarring of the vein. Yes, it takes a little longer to infuse, but what’s another minute?

2. Become proficient infusing ambidextrously. I have learned to infuse using my right or left hand. This just gives you more options.

3. Rotate the veins you use. We all have our favorite veins, but constantly using the same ones will cause them to scar and they may become more difficult to infuse later in life.

4. Hydrate yourself by drinking plenty of fluids before you infuse. Soda pop and other caffeinated beverages dehydrate, so drink water, sports drinks, and fruit or vegetable juices. Veins that are well-hydrated become a bit easier to stick.

5. Relax! Don’t be in a rush. Whatever you have to do will still be there in ten minutes. Concentrate only on the task of getting that factor into your veins (I used to tell my kids I was “powering up”).

6. Try to view your infusion as if you’re infusing someone else. It helps distract you from your own pain and sometimes helps resolve that little bit of flinch that can happen.

7. Do not push down on the needle before or while you are removing it from your vein. Pushing down on the needle while it is still inserted can damage the vein.

8. When the infusion is done, use pressure! Just because the needle is out, the job isn’t done. Put full pressure on the infusion site for at least 30 seconds, then follow with less, but steady pressure for up to another 15 minutes afterwards. This helps reduce those little bruises at the infusion site.

9. On the days you infuse, make an effort to exercise. Push it a little harder on those days. I am a firm believer that the more fit you become, the less injuries you sustain.

10. You’re going to miss! It happens, we’re all human. Eventually, no matter how good you are, you’re going to miss the vein or it’s going to blow on you. It happens, accept it. Don’t doubt yourself, it happens to everyone sooner or later.

I used to think of infusing as a chore, something that was going to take time from my day. Now, it has just become part of life. I might not look forward to it, but it is something necessary to keep me active and going. Now go out and have a good life! I am!

*Always seek the advice of your healthcare providers when making medical decisions.
This article excerpt is reprinted with permission from Matrix Health News, a quarterly publication of Matrix Health Group, Winter 2013, Volume 8, Issue 1, Page 20
**Holiday Party**
Santa Claus visited bearing gifts for the many boys and girls who eagerly anticipated his arrival. Until that time, the bake contest, silent auction, children’s arts and crafts, and music performed by David Pitt and Eric Marcum entertained our guests.

**Scholarship Award**
The spring 2013 Herb Schlaughenhoupt Jr. Memorial Scholarship was awarded to Desmond Shontee of Louisville who attends Indiana State University majoring in Aviation. We are proud of Desmond and congratulate him on his achievements. Desmond is a graduate—so to speak—of KHF’s Camp Discovery, where he spent many summers having fun, making friends, and learning to manage his bleeding disorder.

**Washington Days**
The Marcum family of Louisville, including thirteen year-old Drew and ten year-old Tyler represented KHF at the National Hemophilia Foundation’s advocacy event in Washington, DC in February. They had an opportunity to speak with Kentucky members of Congress and their staff acquainting them with hemophilia and related issues. They sought their support for continued funding of hemophilia treatment centers and the continuation of adequate care for individuals with bleeding disorders and the prevention of insurance pitfalls at the eve of full healthcare reform implementation. Eric Marcum is KHF’s board president and Drew and Tyler both attend KHF’s summer camp.

**Playing a Round for a Cure**
Fifteen teams played a round for a cure at KHF’s annual golf scramble at Oxmoor Country Club on a sunny fall morning. Proceeds from this yearly fundraiser help fund KHF’s program and services for Kentucky’s bleeding disorder’s community. Lunch, dinner, goodie bags, on the course contests, and a silent auction kept our players busy and in good spirits, which were heightened even more by the announcement of winners of an attractive array of prizes. Team winners were Baxter BioScience II, 1st place; Affinity Biotech, 2nd place; and CSL Behring, 3rd place. The putting contest was won by Glen Hitt, Jr.; and the Ball Drop by Warren Rice. The event raised $11,000.
Vegasville
KHF’s Vegas themed gala entertained two hundred guests in mid-winter at the historic and elegant Olmsted building in Louisville. Amidst the glitz and glitter of the décor and the gleaming of evening attire; the musical entertainment by Don Fangman, who performed songs of Vegas legends, and dance music by the Paul Penny Band were superb and set the tone for a splendid evening. Gaming tables and roulette presented ever so aptly by John Silletto and friends proved to be a hit among guests only surpassed by a plethora of must-have auction items and a grand prize drawing for a stunning gold and diamond fleur de lis necklace worth a thousand dollars. The grand prize was donated by JStaples Jewelry. Primary table sponsors were Forcht Bank, Forcht Group of Kentucky, Baxter BioScience, Bayer HealthCare, CSL Behring, and Novo Nordisk. This is KHF’s largest special event fundraiser that raised $28,000.

Spring Flower Sale
Easter lilies, tulips, hyacinths, and mums signaled of the onset of spring as we sold these flowers to many churches and individuals in the Louisville and Lexington areas, Frankfort, Nicholasville, Owensboro, Campbellsville, Lebanon Junction, and southern Indiana. This fundraiser requires the involvement of volunteers in local communities. Without these dedicated volunteers, this fundraiser would not be possible. Janet Goff and Sharon McMahan from Owensboro reign as the top sellers each year. Pat Cooper from Kentucky Blood Center follows a close second. Tina Pelly from Campbellsville, Sadalia Sturgill from Lebanon Junction, and Jenifer Schultz from New Albany also generated sizable orders. We thank these wonderful ladies for their volunteer spirit, commitment to our cause, and hard work.

The sale raised $5,000. This sale can easily be replicated in other communities around the state. Give us a call if you would like to take advantage of this volunteer opportunity and participate in one of our flower sales. We sell poinsettias and spring flowers every year.

Strides for a Cure
Our team relay event in connection with the Kentucky Derby Festival’s Mini-Marathon charity module was a lot of fun and not too taxing. Team members each ran or walked 2.62 miles in support of KHF wearing KHF team t-shirts. They collected pledges from friends and family. Each person received a Mini-Marathon participant shirt and medal. Afterwards, we celebrated their success at Za’s Pizza. Two teams of enthusiastic youngsters from Christian Fellowship were our most vocal and noticeable good will ambassadors. Team sponsors were Baxter, Novo Nordisk, and Pfizer. Corporate contributors were Biogen Idec, CSL Behring, HPC, and Octapharma. The event raised $6,500.
Men's Retreat
This year’s Men’s Retreat brought together men of all ages who participated in two days of animated and enlightening discussions regarding their own or their family’s journey with a bleeding disorder. They also enjoyed the fun times and camaraderie of zip lining, preparing meals, mastering the team challenge course, taking aim at archery, and a well-deserved pizza outing. Watching movies and playing cards in the evening provided subsequent respite. Cedar Ridge proved to be the prefect backdrop for the retreat. Suzi Greer, RN from Baxter and Shelley Gerson from Biogen Idec led the discussions. The event was sponsored by Baxter Bioscience, Biogen Idec, Matrix Health Group, Novo Nordisk, and CSL Behring.

Pledges for the Future of KHF
Kentucky Hemophilia Foundation’s 6th Annual Fund Drive Concluded in 2012 – We thank the following individuals and companies for their generous support

Challenge Gift, $25,000
Mr. & Mrs. Terry Forcht
Corbin, Kentucky

Fundraisers Toward Meeting the Challenge, $5,000+
Nancy Cutrell,
4th Annual Kickathon
In memory of
Terry D. Turner

Strides for a Cure,
2nd Annual KHF Relay Walk/Run

Forcht Challenge Donors, $1,000+
The Community Foundation of Louisville — Made possible by the Zoeller Company

Marion & Terry Forcht
Don & Betty Mattingly

$500 - $999
Charles & Ruth Hall
Roger Harrell, Harrell Locksmith LLC

$100 - $249
Bolton & Company
Herbert Devary, Jr.
Pastor James Deway,
Poinsettia Christmas Cards Sale
Curt E. Flock
Greg Fiscus
Mike Gatton,
In honor of J. Greg Gatton
Fred & Darline Hartman
Dona & Fred Hell,
In honor of the Clark Rhea Family
Thomas R. & Alice Hendrix
Rowen & Ashley Hicks
Curtis & Winnie Jacobs

Michael & Catherine Johnson
Robert & Susan Luxon
Ann Manconi
Mary Marasa
Betty Mattingly
Stuart & Mary Kay Monohan
R. Dale & Kathleen Nichols
Keith Peterson
Sally, Clark, John & Robert Rhea
Charles J. Schroering, Jr.
Donna Steen
John & Pat Tharp
Bradley T. Woods
Gail Yates

$50 - $99
Diane Deitel
Michael Greene
Virginia M. Hamm,
In honor of Sam Charas
Barbara W. Grayson
William & Theresa Harned
Liz Hart
Hebron Presbyterian Church
Glen & Debbie Hitt
Julia Howard
Betty Humphrey,
In honor of Patrick Sanders
Debbie Marasa,
In honor of Jeff Ball
Sandra Osborne
James & Doris Ray
Norma R. Raydon
Ready Cab
George & Renee Wipperman,
Disc Golf Proceeds
Woman of Immanuel/Immanuel United Church of Christ

Up to $49
William E. & Mary Anne Ax
Jo Nell Ballantine

Susan Bosserman
Joshua Brock
James Carrico
Susan K. Gerals
Leroy & Barbara Hendrix
Daniel R. Holibaugh
Donald & Karen Louden
Joan Markwell
Lisa Mattingly, In memory of Danny
Goff and Jeremy Clary
Chris Mayer
William T. Noe
Michael & Glenda Ryan
John C. & Edie Shackelford
David & Georgia Wilson
Ron & Joan Wuetcher,
In honor of Herb Schlaughenhoupt, Jr.

Note: Seventh Annual Fund Drive contributions will be acknowledged at the conclusion of the fund drive in 2013

Donations for the Continuation of Our Memorial Scholarship Program For the Herb Schlaughenhoupt, Jr. Memorial Scholarship

$1,000+
George Schlaughenhoupt
$50 - $100
John & Carol Nord
Gail Yates
Up to $50
Ron & Joan Wuetcher
Gone from our sight but never our memories; gone from our touch but never our hearts…

Josh Baird
Janet & R. Douglas Miller

Anton Edward Burkhardt, III
The Boemker Family
Mark & Carol Briel
Leatha & Dave Brown
Roger Davis & Rhonda Owen
QA Department, NACCO Materials Handling Group
Joe & Linda Renfro
Tri-Medical PLLC/EMSI

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

Spalding Grayson
28 years since his passing
Frances Joyce Lewis
on Christmas
Frances Joyce Lewis
44th birthday
Frances Joyce Lewis

Alan Taylor Hall
Norma & Walter Hall

Fred W. Heil, Jr.
Dona W. Heil

Mrs. Martha Johnson
The Bension Family
Rhelda B. Moore

Kathleen Kearns
Charles & Ruth Hall
Norma & Walter Hall

Betty Lou Mattingly
Jesse & Carol Baird
Margaret J. Baird
Don & Joyce Chancey
Howard & Mary Ann Coddington
Allison & Jason Colvin and The Bryan Family
Christian Builders Class, Lynnhurst United Church of Christ
William & Sharon Crosby
Bill Cominos & Teresa English
Joan M. Farris
Patricia L. Fricke
The Gardner Family, Keith, Jill, J. D, and Katy Jo
Mary Lou Habicht
Diane Haines
Danny & Jeanne Hargrave
Jaimie & Tim Hargrave
Darlene & Stan Hatfield
Sue Hespelt
Betty M. James
Betty Kidd, Keith Kidd, Karen Dixon, and Pat Dixon
Robert & Sandra Kittendorf
June LeMaster
Jane Lockard
Gayle Lucas
Mr. & Mrs. Charles R. Mattingly
Colene J. Mattingly
Denise Mattingly
Irv Maze
Janet & R. Douglas Miller
Becky & Pat Murphy
William Noe

Larry & Brigitte Oslin
Ann Ray
Doris & James Ray
Jim & Deanna Ray and Family
Lauren Savage
Sheri Sampson
Mike & Jennifer Schultz
Martha Szymansky
Lorraine & Ken Smith
Linda June Stammen
Margaret, Butch, Rose, Kristen, and Madison Staples
Gary & Diana Thalacker
Marvin & Wanda Wenz and Sharp Family
Carol White
Donald & Nina Wilkinson
Myra Winstead
Neal & Denny Meadors
Janet & R. Douglas Miller

William & Martha Nord
John & Carol Nord

Herb & Henrietta Schlaughenhaupt
John & Carol Nord

Herb Schlaughenhaupt, Jr.
Ron & Joan Wuetcher

Marian Turner, RN
Robin Brown
Steven & Laura Koenig

And More....
KHF has many fun events throughout the year. Join Us!
KHF neither recommends nor endorses the products in this publication and does not make recommendations concerning treatment regimen for individuals. KHF suggests that you consult your physician or treatment center before pursuing any course of treatment. This publication is for general information only.

**Do The Five**

Follow these steps to prevent or reduce complications of bleeding disorders

1. Get an annual comprehensive checkup at a hemophilia treatment center.
2. Get vaccinated – Hepatitis A and B are preventable.
3. Treat bleeds early and adequately.
4. Exercise to protect your joints.
5. Get tested regularly for blood-borne infections.

To find out more about the National Prevention Program developed by the National Hemophilia Foundation in collaboration with the Centers for Disease Control and Prevention (CDC), click on [www.hemophilia.org](http://www.hemophilia.org) or call toll-free 800-42-HANDI.

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**Top 10 Primary Supporters for the Fiscal Year Ending in 2012**

**Terry & Marion Forcht**

**Baxter BioScience**

**Kosair Charities**

**Pfizer**

**Bayer HealthCare**

**Novo Nordisk**

**Affinity**

**CSL Behring**

**Grifols**

**Octapharma**

*Thank you all for your generous support and commitment to our cause.*
BAYER HEALTHCARE AND THE HEMOPHILIA COMMUNITY:

Commitment, Leadership and Innovation
In a clinical study, after switching from 6 months of on-demand treatment to 12 months of prophylaxis with ADVATE in 53 previously treated patients with severe or moderately severe hemophilia A.

**ADVATE is the only recombinant factor VIII (eight) that is FDA approved for prophylaxis in both adults & children (0-16 years)**

**Significant reduction in median annual bleed rate (ABR) with prophylaxis treatment compared with on-demand treatment**

- 0 bleeds experienced by 42% of patients during 1 year on prophylaxis.
- 98% reduction in median annual bleed rate (ABR) from 44 to 1 when switched from on-demand to prophylaxis.
- 97% reduction in joint bleeds from 38.7 to 1 after switching from on-demand to prophylaxis.
- No subject developed factor VIII inhibitors or withdrew due to an adverse event.

**Detailed Important Risk Information for ADVATE**

You should not use ADVATE if you are allergic to mice or hamsters or any ingredients in 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 and dietary supplements, have any allergies, including allergies to mice or hamsters, are nursing, are pregnant, or have been told that you have 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.

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.

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

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

**Indication for ADVATE**

ADVATE [Antihemophilic Factor (Recombinant), Plasma/Albumin-Free Method] is a medicine used to replace clotting factor VIII 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.

Please see Brief Summary of ADVATE Prescribing Information 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.

**References:**

INDICATIONS AND USAGE
Control and Prevention of Bleeding Episodes
ADVATE [Antithemophilic Factor (Recombinant), Plasma/Albumin-Free Method] is an Antithemophilic Factor (Recombinant) indicated for control and prevention of bleeding episodes in adults and children (0-16 years) with Hemophilia A.

Perioperative Management
ADVATE is indicated in the perioperative management in adults and children (0-16 years) with Hemophilia A.

Routine Prophylaxis
ADVATE is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children (0-16 years) with Hemophilia A. ADVATE is not indicated for the treatment of von Willebrand disease.

CONTRAINDICATIONS
Known anaphylaxis to mouse or hamster protein or other constituents of the product.

WARNINGS AND PRECAUTIONS
Anaphylaxis and Hypersensitivity Reactions
Allergic-type hypersensitivity reactions, including anaphylaxis, are possible and have been reported with ADVATE. Symptoms have manifested as dizziness, paranoid/paranoid, rash, flushing, face swelling, urticaria, dysnea, and pruritus. [See Patient Counseling information (17) in full prescribing information]

ADVATE contains trace amounts of mouse immunoglobulin G (M IgG): maximum of 0.1 ng/mL ADVATE and hamster proteins: maximum of 1.5 ng/mL 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
Carefully monitor patients treated with AHF products for the development of Factor VIII inhibitors by appropriate clinical observations and laboratory tests. Inhibitors have been reported following administration of ADVATE predominantly in previously untreated patients (PUPs) and previously minimally treated patients (MTPs). 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 (5.3) in full prescribing information]

Monitoring Laboratory Tests
The clinical response to ADVATE may vary. If bleeding is not controlled with the recommended dose, determine the plasma level of Factor VIII and administer a sufficient dose of ADVATE to achieve a satisfactory clinical response. If the patient’s plasma Factor VIII level falls to increase as expected or if bleeding is not controlled after the expected dose, suspect the presence of an inhibitor (neutralizing antibody) and perform appropriate tests as follows:

• Monitor plasma Factor VIII activity levels by the one-stage clotting assay to confirm the adequate Factor VIII levels have been achieved and maintained when clinically indicated. [See Dosage and Administration (2) in full prescribing information]

• 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 titrate inhibitors.

• If the inhibitor titer is less than 10 BU/mL, the administration of additional Antithemophilic Factor Concentrate may neutralize the inhibitor and may permit an appropriate hematologic response.

• If the inhibitor titer is above 10 BU/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 drug reactions (ADRs) seen with ADVATE are hypersensitivity reactions and the development of high-titer inhibitors necessitating alternative treatments to Factor VIII.

The most common ADRs 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 studies in previously treated patients (PTPs) and one ongoing study 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 44,926 infusions. The median duration of participation per subject was 370.3 (range: 1 to 1,258) days and the median number of exposure days to ADVATE per subject was 128.0 (range: 1 to 982).

The summary of adverse reactions (ADRs) with a frequency ≥5% is shown in Table 2.

In clinical studies that enrolled previously untreated subjects (defined as having had up to 3 exposures to a Factor VIII product at the time of enrollment), 5 (20%) of 25 subjects who received ADVATE developed antibodies to Factor VIII. Four patients developed antibodies to Factor VIII (>5 BU/mL) and one patient developed low-titer inhibitors. Inhibitors were detected at a median of 11 exposure days (range 7 to 13 exposure days) to investigational product.

Immuneogenicity also was evaluated by measuring the development of antibodies to heterologous proteins. 192 treated subjects were assessed for anti-Chinese hamster ovary (CHO) cell protein antibodies. Of these, 3 showed and upward trend in antibody titer over time and 4 showed repeated but transient elevations of antibodies. 182 treated subjects were assessed for mAb33 protein antibodies. Of these, 10 showed a transient trend in anti-mAb33 antibody titer over time and 2 showed repeated but transient elevations of antibodies. Four subjects who demonstrated antibody elevations reported isolated events of urticaria, pruritus, rash, and slightly elevated eosinophil counts. All of these subjects had numerous repeat exposures to the study product without recurrence of the events and a causal relationship between the antibody findings and these clinical events has not been established.

Of the 181 subjects who were treated and assessed for the presence of anti-human von Willebrand Factor (VWF) antibodies, none displayed laboratory evidence indicative of a positive serologic response.

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 2 represents the most frequently reported post-marketing adverse reactions as MedDRA Preferred Terms. Table 1

Table 1 Summary of Adverse Reactions (ADRs) with a Frequency ≥5% in 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>
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<tr>
<td>General disorders and administration site conditions</td>
<td>Pyrexia</td>
<td>78</td>
<td>90</td>
<td>21</td>
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<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>Cough</td>
<td>75</td>
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<tr>
<td>Infections and infestations</td>
<td>Nasopharyngitis</td>
<td>61</td>
<td>40</td>
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<td>Musculoskeletal and connective tissue disorders</td>
<td>Arthralgia</td>
<td>44</td>
<td>27</td>
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<tr>
<td>Injury, poisoning and procedural complications</td>
<td>Limb injury</td>
<td>55</td>
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<td>Respiratory, thoracic and mediastinal disorders</td>
<td>Pharyngolaryngeal pain</td>
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<tr>
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<td>Nasal congestion</td>
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<tr>
<td>Gastrointestinal disorders</td>
<td>Diarrhea</td>
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<td>General disorders and administration site conditions</td>
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<td>Skin and subcutaneous tissue disorders</td>
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</tr>
</tbody>
</table>

MedDRA version 11.1 was used.

Table 2 Post-Marketing Experience

<table>
<thead>
<tr>
<th>Organ System [MedDRA Primary SOC]</th>
<th>Preferred Term</th>
<th>Term Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immune system disorders</td>
<td>Anaphylactic reaction*</td>
<td>Hypersensitivity**</td>
</tr>
<tr>
<td>Blood and lymphatic system disorders</td>
<td>Factor VIII inhibition</td>
<td></td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>Injection site reaction</td>
<td>Fatigue/Malaise</td>
</tr>
<tr>
<td></td>
<td>Chest discomfort/pain</td>
<td>Less-than-expected therapeutic effect</td>
</tr>
</tbody>
</table>

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

**These ADRs are defined as Adverse Events that occurred up to 24 hours after being treated with investigational product or by (2) Adverse Events assessed as related or possibly related to investigational product or (3) Adverse Events for which the investigator’s or operator’s opinion of causality was missing or indeterminate.

The ADVATE clinical program included 234 treated subjects from 5 completed studies in PTPs and 1 ongoing study in PUPs as of 27 March 2006.


To enroll in the confidential, industry-wide Patient Notification System, call 1-888-873-2383.

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Patented under U.S. Patent Numbers: 5,733,873; 5,845,021; 5,919,766; 5,955,448; 6,313,102; 6,586,573; 6,649,386; 7,087,723; and 7,247,707. Made according to the method of U.S. Patent Numbers: 5,470,954; 6,100,061; 6,475,725; 6,555,391; 6,836,441; 7,094,574; 7,253,282; and 7,381,796.

Baxter Healthcare Corporation, Westlake Village, CA 91362 USA

U.S. License No. 140 Printed in USA Issued July 2012
BAYER HEALTHCARE AND THE HEMOPHILIA COMMUNITY:
Commitment, Leadership and Innovation
For the treatment of von Willebrand Disease

I will take control of my VWD

vilate® is a von Willebrand Factor/Coagulation Factor VIII Complex (Human) indicated for the treatment of spontaneous and trauma-induced bleeding episodes in patients with severe von Willebrand disease (VWD), as well as patients with mild or moderate VWD in whom the use of desmopressin is known or suspected to be ineffective or contraindicated.

I will take my kids to the beach today

I will wear my new white sundress

I will expect more from my von Willebrand factor treatment

Important Safety Information:

vilate® is contraindicated for individuals with a history of anaphylactic or severe systemic reaction to human plasma-derived products, any ingredient in the formulation, or components of the container. Thromboembolic events have been reported in VWD patients receiving coagulation factor replacement therapies. FVIII activity should be monitored to avoid sustained excessive FVIII levels. vilate® is made from human plasma. The risk of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease agent, cannot be completely eliminated. The most common adverse reactions to treatment with vilate® in patients with VWD have been urticaria and dizziness. The most serious adverse reactions to treatment with vilate® in patients with VWD have been hypersensitivity reactions.

To report suspected adverse reactions, contact:
Octapharma USA, Inc.
866-766-4860 or
FDA at 1-800-FDA-1088 or
www.fda.gov/medwatch

Please see the Highlights of Prescribing Information on the adjacent page.
HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Wilate safely and effectively. See full prescribing information for Wilate.

Wilate, von Willebrand Factor/Coagulation Factor VIII Complex (Human), Powder for Solution, for Intravenous Use Only. Initial U.S. Approval: 2009

INDICATIONS AND USAGE

- Wilate is a von Willebrand Factor/Coagulation Factor VIII Complex (Human) indicated for the treatment of spontaneous and trauma-induced bleeding episodes in patients with severe von Willebrand disease (VWD) as well as patients with mild or moderate VWD in whom the use of desmopressin is known or suspected to be ineffective or contraindicated.
- Wilate is not indicated for the prophylaxis of spontaneous bleeding episodes, or the prevention of excessive bleeding during and after surgery in VWD patients.
- Wilate is also not indicated for Hemophilia A

DOSAGE FORMS AND STRENGTHS

- Wilate is a sterile, lyophilized powder for reconstitution for intravenous injection, provided in the following nominal strengths per vial:
  - 500 IU VWF:RCo and 500 IU FVIII activities in 5 mL
  - 1000 IU VWF:RCo and 1000 IU FVIII activities in 10 mL

CONTRAINDICATIONS

- Hypersensitivity with known anaphylactic or severe systemic reaction to human plasma-derived products, any ingredient in the formulation, or components of the container.

WARNINGS AND PRECAUTIONS

- Hypersensitivity reaction
- Thromboembolic events associated with von Willebrand factor/Coagulation Factor FVIII (VWF/FVIII) products: plasma levels of FVIII activity should be monitored to avoid sustained excessive FVIII levels, which may increase the risk of thrombotic events
- Potential for inducing antibodies to Factor VIII (inhibitors) and antibodies to VWF, especially in VWD type 3 patients
- Theoretical risk of infectious agents transmission as the product is made from human plasma

ADVERSE REACTIONS

The most common adverse reactions in clinical studies on VWD were urticaria and dizziness (each 2.2%) (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Octapharma USA Inc. at phone # 866-766-4860 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- None known.

USE IN SPECIFIC POPULATIONS

- Pregnancy: No human or animal data. Use only if clearly needed.

DOSEAGE AND ADMINISTRATION

For Intravenous Use after Reconstitution

- Treatment should be initiated under the supervision of a physician experienced in the treatment of coagulation disorders.
- Each vial of Wilate contains the labeled amount in International Units (IU) of von Willebrand factor (VWF) activity as measured with the Ristocetin cofactor assay (VWF:RCo), and coagulation factor VIII (FVIII) activity measured with the chromogenic substrate assay.
- The number of units of VWF:RCo and FVIII activities administered is expressed in IU, which are related to the current WHO standards for VWF and FVIII products. VWF:RCo and FVIII activities in plasma are expressed either as a percentage (relative to normal human plasma) or in IU (relative to the International Standards for VWF:RCo and FVIII activities in plasma).

Dosage in von Willebrand Disease

The ratio between VWF:RCo and FVIII activities in Wilate is approximately 1:1.

- The dosage should be adjusted according to the extent and location of the bleeding. In VWD type 3 patients, especially in those with gastro-intestinal (GI) bleedings, higher doses may be required.

Dosing Schedule

Physician supervision of the treatment regimen is required. A guide for dosing in the treatment of major and minor hemorrhages is provided in Table 1. The careful control of replacement therapy is especially important in life-threatening hemorrhages. When using a FVIII-containing VWF product, the treating physician should be aware that continued treatment may cause an excessive rise in FVIII activity.

Table 1 Guide to Wilate Dosing for Treatment of Minor and Major Hemorrhages

<table>
<thead>
<tr>
<th>Type of Hemorrhages</th>
<th>Loading Dosage (IU VWF:RCo/kg BW)</th>
<th>Maintenance Dosage (IU VWF:RCo/kg BW)</th>
<th>Therapeutic Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor Hemorrhages</td>
<td>20-40 IU/kg</td>
<td>20-30 IU/kg every 12 – 24 hours*</td>
<td>VWF:RCo and FVIII activity through levels of &gt;30%</td>
</tr>
<tr>
<td>Major Hemorrhages</td>
<td>40-60 IU/kg</td>
<td>20-40 IU/kg every 12 – 24 hours*</td>
<td>VWF:RCo and FVIII activity through levels of &gt;50%</td>
</tr>
</tbody>
</table>

Treatment guidelines apply to all VWD types

*This may need to be continued for up to 3 days for minor hemorrhages and 5-7 days for major hemorrhages

Repeat doses are administered for as long as needed based upon repeat monitoring of appropriate clinical and laboratory measures.

Although dose can be estimated by the guidelines above, it is highly recommended that whenever possible, appropriate laboratory tests should be performed on the patient’s plasma at suitable intervals to assure that adequate VWF:RCo and FVIII activity levels have been reached and are maintained.

In the unlikely event that a patient who is actively bleeding should miss a dose, it may be appropriate to adopt a dosage depending on the level of coagulation factors measured, extent of the bleeding, and patient’s clinical condition.

HOW SUPPLIED/STORAGE AND HANDLING

- Wilate is supplied in a package with a single-dose vial of powder and a vial of diluent (Water for Injection with 0.1% Polysorbate 80), together with a Mix2Vial™ transfer device, a 10-mL syringe, an infusion set and two alcohol swabs.
- Each vial of Wilate contains the labeled amount of IU of VWF:RCo activity as measured using a manual agglutination method, and IU of FVIII activity measured with a chromogenic substrate assay.
- Components used in the packaging of Wilate contain no latex.

Shelf life

- Store Wilate for up to 36 months at +2°C to +8°C (36°F to 46°F) protected from light from the date of manufacture. Within this period, Wilate may be stored for a period of up to 6 months at room temperature (maximum of +25°C or 77°F). The starting date of room temperature storage should be clearly recorded on the product carton. Once stored at room temperature, the product must not be returned to the refrigerator. The shelf-life then expires after the storage at room temperature, or the expiration date on the product vial, whichever is earliest. Do not freeze.
- Do not use after the expiration date.
- Store in the original container to protect from light.
- Reconstitute the Wilate powder only directly before injection. Use the solution immediately after reconstitution. Use the reconstituted solution on one occasion only, and discard any remaining solution.

PATIENT COUNSELING INFORMATION

- Inform patients of the early signs of hypersensitivity reactions including hives, generalized urtication, tightness of the chest, wheezing, hypotension, and anaphylaxis. If allergic symptoms occur, patients should discontinue the administration immediately and contact their physician.

Manufactured by:

Octapharma Pharmazeutika Produktionsges.m.b.H. Oberlaaer Strasse 235 A-1100 Vienna, Austria U.S. License No. 1646

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