Infusions

NEWSLETTER OF THE HEMOPHILIA FOUNDATION OF NORTHERN CALIFORNIA · SUMMER 2014

PHOTO BY CHRISTINA BERUMEN

A spy was among us at Camp Hemotion!

Camp Hemotion had another successful year as our 37th annual program brought back old traditions and saw new ideas take their place in our rich history.

This year's theme, secret agents, brought a pair of spies into camp, as the campers were given clues throughout the week in their effort to discover "The Mole." Suspicions ran high as any irregularity was taken as evidence to brand one of the staff members a "SUSPECT!"

It was revealed at our final campfire Friday night that the moles were in fact Christina and Renee, our Arts & Crafts directors! Fortunately, it turns out they were only spying on us to take the great things happening at Camp Hemotion and spread them to other camps around the country! All was forgiven in the end.

The rest of the week was filled with swimming, archery, high ropes, and, of course, gaga.

As part of the mission of HFNC and our camp, we continued to encourage young people with bleeding disorders to take control of their lives by learning to infuse themselves. This year, a total of 14 individuals earned their Big Stick award, infusing themselves for the first time, ranging in age from 7 to 19!

We also handed out the second installment of the Todd Smith Awards, given to the most outsanding staff member and the camper who most exemplifies the spirit of Camp Hemotion.

David Cheung earned the staff award for his leadership amongst the junior staff, as he took charge of chaperooning the train ride for the junior and assistant counselors and helped lead the planning and implementation of our theme night during camp.

The camper award went to Caleb Crother, a long-time camper who will be eligible to be a junior counselor next year. We look forward to watching Caleb take the next steps in his development.

For more pictures from camp, check out pages six and seven.

Transition time at HFNC

By Merlin Wedepohl

I have retired as of June 27. It has been a real pleasure to serve HFNC as your Executive Director since March 2008. Thank you for embracing me as part of this special community these past six years. I have been so fortunate to get to know you all and observe your children grow into wonderful, caring and giving young adults. Each of you has taught me so much about how to cope with a chronic disorder with grace and mutual support for each other. You have been an inspiration to me.

Claudia and I have decided to make our primary home for retirement in Bellingham, Washington where my mother currently lives. We probably will move in late summer. If our house sells in Napa, we may be able to have a small condo in Napa as well. It is my intention to keep in touch with you all and show up on occasion for some of your great events.

HFNC has hired an outstanding person with experience in the non-profit industry to be your new Executive Director. The HFNC Board of Directors allowed Patrick and I to have six weeks of overlap, hense this transition in leadership has gone very smoothly. Please welcome Patrick into your midst as you did me. Together you will make great things happen.

By Patrick Dunlap

Thank you everyone for the warm welcome to the hemophilia community as the new Executive Director for the Hemophilia Foundation Northern California. I have been a busy bee making strides, learning the hemophilia community and meeting all the families.

Over the past month I have had some great experiences. One of my most memorable was at Camp Hemotion, spending time with all of the campers, volunteers and directors. I was even introduced to the gaga pit and was schooled by several campers.

It was great to see how the program, over the past 37 years, has positively impacted the lives of those that have bleeding disorders. The camp has allowed the campers to have a wonderful time with friends in a safe environment.

I have been in the non-profit world for 19 years. Most recently I was the Executive Director for the American Diabetes Association. In years past I led the Cystic Fibrosis Foundation as Executive Director, Arthritis Foundation as Vice President of Development and started as a telemarketer in non-profit at the March of Dimes. I have many personal connections to other wonderful organizations and also enjoy volunteering in the community.

I have a wonderful and supportive family. My wife, Jackie, and I have been together for 20 years, married for over 15 years. We have a 12-year-old daughter and a 7-year-old son.

My mottos to help us rally behind our mission are:

- Mission-driven but revenue-dependent
- Quality not quantity
- Make it an experience

I look forward to working with all of you, I am very excited about what the future holds for the hemophilia community.

Contact Information

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Office hours: Mon-Fri,
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www.hemofoundation.org

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Donate your vehicle to support NHF and HFNC

Donate your car, boat, motorcycle, truck or other vehicle to NHF's Vehicle Donation Program. Visit NHF at www.hemophilia.org and click the "vehicle donation program" link, or call 1 (855) NHF-4-CAR. A representative will explain all of the details — including how to schedule free pick-up service that's convenient for you.

HFNC is going green!

Help HFNC reduce waste and cost by receiving *Infusions* via email. If you would like to make the switch, please email Merlin Wedepohl at merlin.wedepohl@hemofoundation.org.

Creating a Lifeline of Community and Support

Dr. K Leaves Legacy at Camp

By Bobby Wiseman

After 37 years of tireless service, Dr. Marion Koerper informed HFNC leadership that she will be stepping down as Medical Director of Camp Hemotion.

The program has served the youth and children in the Northern and Central California regions with a robust and vibrant camping experience. At the helm of the medical component throughout its history has been Dr. K, as she is known to campers and staff alike. Dr. K has been a friend, mentor, advocate and champion for the bleeding disorders for many, many years.

In her role as Medical Director for Camp Hemotion (formerly Camp Caz) she has provided exemplary care for those with bleeding disorders in a caring and compassionate manner. She has advocated for the various needs of the community on a local, regional and national level.

Many campers can remember learning about the coagulation cascade from her highly interactive train model for coagulation. As we aged she instructed us on the genetics of hemophilia and von Willebrand's disease. Within the camping environment many campers would ask questions that they may not have been comfortable asking their respective HTC staff about their bleeding disorder, yet during the camping experience they felt safe and comfortable enough to ask the tough questions. Dr. K replied with great zeal and energy, giving participants the complete information sothey could be better-informed consumers and thereby better self-advocates.

FILE PHOTO

Thanks to Dr. K, many generations will forever explain their bleeding disorder using a train as an analogy.

In a time when women with bleeding disorders were not addressed on a national basis, Dr. K brought to the forefront the various issues that women with bleeding disorders face in the camp setting. Participants were able to connect with other members of the community and form a strong sisterhood from her medical education sessions during camp.

Not only is Dr. K an accomplished physician, she is a superb ice skater, mother, wife and grandmother. She is a true asset to the bleeding disorders community.

She spearheaded the effort to start a camp in Northern California for those with bleeding disorders. The camp started out with a handful of campers and has since grown to its current level of sreving over 70 campers every year. She has championed the need to assist children in learning to self-infuse so hey may become independent. She has trained countless individuals in the medical arena on the appropriate care and management of hemophilia, von Willebrand's and related bleeding and clotting disorders.

Her tireless dedication of the last 37 years will not be forgotten. She has provided sound medical and practical advice to all who have attended Camp Hemotion in our 37 years of service. Dr. K will truly be missed from the Camp Hemotion program, but never forgotten.

Calendar

August

4 Board meeting (phone) 6:30 - 8:30 p.m.
10 HCC California Advocacy Summit 10 a.m.
10 Wine Tasting Event 4:00 pm
11 Golf Tournament
14 Baxter Facts First - Emeryville 6:30 p.m.
17-23 HCC Bike ride to San Diego
24 Taylor Family Day in the Park

September

8 Board meeting (in person) 6:30 - 8:30 p.m.
11 Baxter Facts First – Concord 6:30 p.m.
18-20 NHF Annual Meeting – Washington, D.C.

October

13 Board Meeting (phone) 6:30 - 8:30 p.m.
11 Asian Infusion (Grifols) – Oakland Noon
19 Hispanic Heritage Celebration (San Jose) 11 a.m. – 6 p.m.

November

10 Board meeting (in person) 6:30 - 8:30 p.m.
13 Biogen Idec Hemophilia – Peninsula 6:30 p.m.
20 Bayer – Oakland 6:30 p.m.

Study Stresses Inhibitor Screening

Results from a six-year study of patients with hemophilia A and B produced interesting findings.

The Hemophilia Inhibitor Research Study (HIRS) enrolled 1,163 patients from 17 federally funded hemophilia treatment centers (HTCs). One of the goals was to predict which patients were at highest risk for development of inhibitors, antibodies to infused factor.

"A Study of Prospective Surveillance for Inhibitors Among Persons with Haemophilia in the United States," was published in the March 2014 issue of Haemophilia. The lead investigator was Michael Soucie, PhD, Division of Blood Disorders, National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention (CDC) in Atlanta.

A central laboratory performed periodic inhibitor tests using blood samples and genotyped the subjects. In all, 3048 inhibitor tests (some patients were screened more than once) were conducted. The main findings were:

- All people with hemophilia are at risk for developing inhibitors
- One-third of newly developed inhibitors were found in people with non-severe hemophilia
- One-half were older than 5 years old
- Six out of 10 people with hemophilia with an inhibitor had no symptoms
- 23 new FVIII inhibitors were identified
- 431 distinct mutations were genotyped, 151 of which had not previously been reported

HIRS investigators and CDC researchers determined that individuals with hemophilia of all ages were at risk for developing an inhibitor. Further, CDC now estimates that approximately 60% of people with an inhibitor have no symptoms.

Without regular screening, a significant number of these patients may not be aware of it until they experience severe bleeding.

The CDC concluded that patients with hemophilia receiving care in federally funded HTCs will be tested yearly for an inhibitor by the CDC Division of Blood Disorders laboratory as part of Community Counts, its new blood monitoring program.

Source: CDC

Politicking in Sacramento

Advocates for the bleeding disorders community stormed Sacramento in May to visit legislators' offices in support of motions going before the state legislature that will affect our community.

Among the pieces of legislation we supported were movements to limit drug costs to patients by spreading out co-pays over time, allowing patients to opt out of mail-order prescription restrictuions, and requiring health plans to list drug formularies on their websites.

The trip also included a unique opportunity for our "Future Leaders," as teens from around the state were trained to share their stories with the legislators in an effort to bring the human element to our cause.

COURTESY PHOTO

COURTESY PHOTO

Back in Action at the Ballpark

Dads of children with bleeding disorders attended an Oakland A's game in June as part of the Hemophilia Federation of America's Dads in Action program.

This great event was booked full, a promising sign for future events as the program continues to build networking opportunities for fathers and giving them an opportunity to get some qality time with their children.

HFNC hosted our annual Hemophilia Walk, in partnership with NHF, on April 19 at Cesar Chavez Park in Berkeley.

With 806 walkers spread over 36 teams, we were able to raise more than $100,000 thanks in part to the following sponsors:

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SILVER

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BRONZE

Octopharma
Walgreens

RIGHT: The oldest boys cabin holds court before mealtime. BELOW (clockwise from top left): A competitive game of gaga, one of our camp's oldest traditions. Three generations of camp pose for a picture as a junior staff, senior staff and camper flash their smiles. The basketball tournament saw some flashymoves. A camper explains some important information about a clue to the spy's identity to one of the camp directors.

The annual baseball lunch brought out the best (or worst, depending on your fashion sense) in both Giants fans and A's fans as we sang "Take Me Out to the Ball Game" and the National Anthem.

TOP LEFT: The camp directors and senior staff after the campwide water fight. TOP RIGHT: Two campers after diving face-first into a whip cream pie looking for bubble gum. BOTTOM RIGHT: If your table is not clean, you get the onion. Eat it, eat it! BOTTOM LEFT: A camper brushes up on her facepainting skills by practicing on her junior counselor.

ALL PHOTOS BY CHRISTINA BERUMEN AND ANDY BLACKLEDGE

FDA Approves First Long-acting Factor 9 Therapy

In March, Biogen Idec announced that the US Food and Drug Administration (FDA) approved ALPROLIXTM, the company's long-acting, recombinant factor IX (rFIX) Fc fusion protein therapy. The product, the first long-acting rFIX therapy, is indicated for the control and prevention of bleeding episodes, perioperative (surgical) management and routine prophylaxis in adults and children with hemophilia B. The therapy has shown to reduce bleeding episodes with weekly prophylactic infusions. It is the first significant improvement in hemophilia B therapies in 17 years.

Approval of ALPROLIXTM was based on Phase 3 results from the B-LONG clinical studies in adolescents and adults with hemophilia B. Subjects demonstrated a prolonged circulation of rFIX in the body, lengthening the intervals between prophylactic infusions. The median overall dosing interval for those in the prophylaxis arm was 12.5 days. Further, more than 90% of bleeds were controlled by one infusion of the rFIX therapy. No participants developed an inhibitor to the product.

"The FDA approval of ALPROLIX is a significant milestone for the hemophilia B community, and represents an important first step in our commitment to transform the care of people with hemophilia," said George A. Scangos, PhD, chief executive officer of Biogen Idec. "ALPROLIX offers people with hemophilia B the ability to prevent or reduce bleeding episodes with prophylactic infusions starting at least a week apart. We believe this new therapy will help more people with hemophilia and their caregivers realize the benefits of this treatment approach."

"Hemophilia has a significant impact on people whom it affects, throughout their lives," said Patrick F. Fogarty, MD, assistant professor of medicine at the Hospital of the University of Pennsylvania, and director, Penn Comprehensive Hemophilia and Thrombosis Program.

"ALPROLIXTM addresses a critical need by allowing people with hemophilia B to maintain factor levels with prophylactic infusions once weekly or once every 10 days. We hope this will facilitate use of prophylactic therapy."

Health Canada also announced the approval of ALPROLIXTM on March 21, 2014. Biogen expects its new product to be commercially available in May.

Sources: Biogen press release dated March 28, 2014; Business Wire press release dated March 28, 2014

COURTESY PHOTO

NHF Highlights New Chapter of Nurses' Guide

In April 2014, the National Hemophilia Foundation (NHF) highlighted another new chapter of The Nurses' Guide to Bleeding Disorders (NGBD), which provides comprehensive information and practical ideas to assist nurses at all levels in caring for patients with bleeding disorders. This chapter, written by Susan Geraghty, RN, MBA, focuses on orthopedic issues relevant chronic joint bleeding.

In "Orthopedic Complications and Treatment Related to Chronic Hemarthrosis," Geraghty provides a baseline explanation of target joints and hemophilic arthropathy, the debilitating and painful joint disease resulting from chronic bleeding into a patient's joints such as the knee, elbow, ankle and hip. She goes on to describe the highly sensitive tools that can now be employed in joint assessment, including radiographic imaging [ultrasound, CT scan and magnetic resonance imaging (MRI)] and the subsequent application of effective classification systems/joint scores. Geraghty also emphasizes the importance of comprehensive care as a robust response to chronic hemarthrosis and a helpful way to ameliorate its degenerative affects.

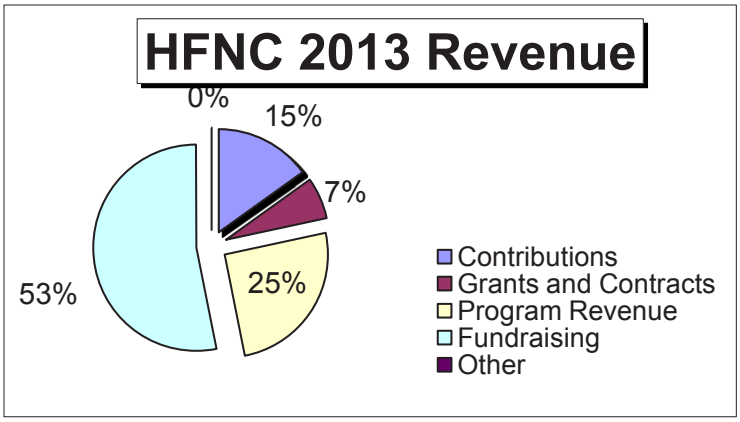
Over the last several years, the NGBD has further evolved into a readily accessible online resource, serving as an introduction to nurses new to coagulation and an information source for more experienced nurses.

New chapters, which continue to be uploaded in downloadable PDF format, cover a wide range of topics such as von Willebrand disease, rare bleeding disorders, hepatitis, orthopedics and women with bleeding disorders.

To access and download this and other chapters go to the NHF web site at www.hemophilia.org.

2013FINANCIALS

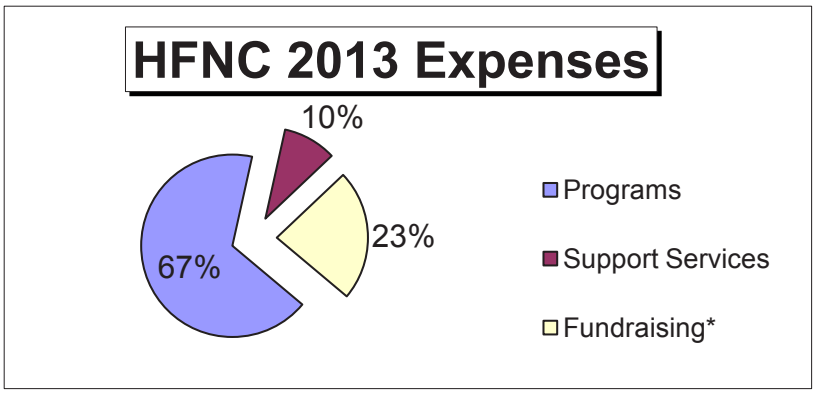
Revenue	
Contributions	$69,407
Grants and Contracts	$30,000
Program Revenue	$116,113
Fundraising	$243,989
Other	$332
TOTAL REVENUES	**$459,841**



Expenses	
Programs	$391,670
Support Services	$54,991
Fundraising*	$134,714
TOTAL EXPENSES	**$581,375**

includes special events

Change in net assets	**-5,705**



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$20,000-60,000

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Creating a Lifeline of Community and Support

Bats, balls and bleeders

On Saturday, July 26, the second annual HFNC Baseball Clinic was held in San Mateo. The clinic was led by Robert McDowell, a community member with severe hemophilia B, and his baseball buddy Sean Ghazarian.

Robb is 22 years old and has grown up playing baseball. A dedicated athlete in both high school and college, he is a great role model for the young men and women who attended the clinic. Clinic participants engaged in warm up and stretching exercises, were taught proper throwing and catching techniques, did infield and outfield drills and practiced batting.

After a delicious BBQ lunch cooked by Chef Oscar Pacheco, the kids

enthusiastically returned to the field for an exciting practice game with the parents. A fun time was had by all who attended. Many thanks to our sponsors the Wingmen Foundation and C.J. Wilson's Children's Charities. Also to clinic organizers Brent Mascorro, Yolanda Pacheco, Barbara Harvey and everyone who helped make the day a great success.

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PROPHYLAXIS WITH ADVATE REDUCED BLEEDS IN A CLINICAL STUDY[1,a]

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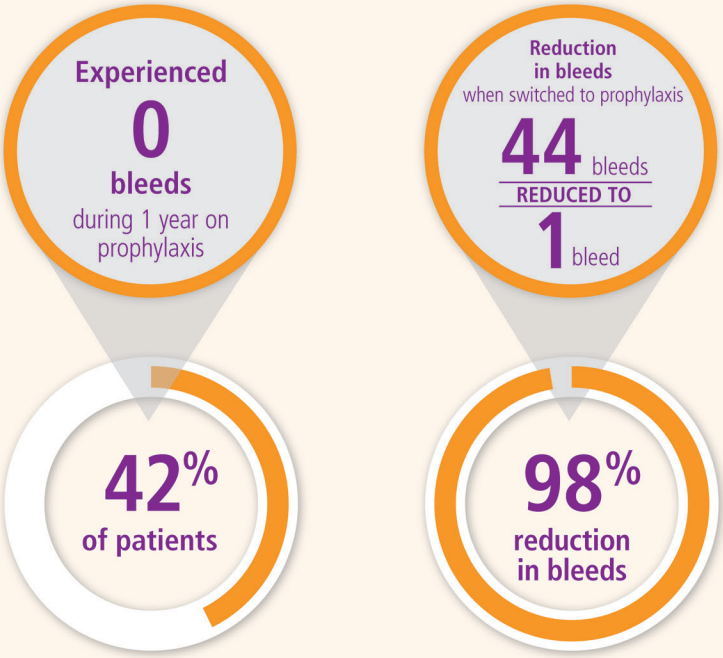
Significant reduction in median annual bleed rate (ABR) with prophylaxis treatment compared with on-demand treatment[1,a]



- 0 bleeds experienced by 42% of patients during 1 year on prophylaxis[1,a]
- 98% reduction in median annual bleed rate (ABR) from 44 to 1 when switched from on-demand to prophylaxis[1,a]
- 97% reduction in joint bleeds from 38.7 to 1 after switching from on-demand to prophylaxis[1,a]
- No subject developed factor VIII inhibitors or withdrew due to an adverse event (AE)[2,a]

[a]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.

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.

References:

1. ADVATE Prescribing Information. Westlake Village, CA: Baxter Healthcare Corporation; July 2012. **2.** Valentino LA, Mamonov V, Hellmann A, et al. A randomized comparison of two prophylaxis regimens and a paired comparison of on-demand and prophylaxis treatments in hemophilia A management. *J Thromb Haemost*. 2012;10(3):359-367. **3.** PROLabels: patient-reported outcomes & drug marketing authorizations. ProLabels Web site. http://www.mapi-prolabels.org. Accessed June 5, 2012. **4.** Maruish ME, ed. *User's Manual for the SF-36v2 Health Survey*. 3rd ed. Lincoln, RI: QualityMetric Incorporated; 2011.

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AND PROVIDED CLINICALLY MEANINGFUL IMPROVEMENTS[b] IN PHYSICAL HEALTH-RELATED QUALITY OF LIFE[1]

ADVATE is the only recombinant factor VIII with physical health-related quality of life results[3,c]

Overall improvement in physical functioning, well-being, general health, and/or energy level, based on Physical Component Score.[4]

Reduced levels of pain and improvements in the limitations of work due to pain.[4]

BODILY PAIN

Improvements in the ability to perform work or other daily activities.[4]

ROLE PHYSICAL

PHYSICAL FUNCTIONING

Changes not observed in limitations to a range of minor and major physical activities.[4]

GENERAL HEALTH

Changes not observed in the views and expectations of overall health.[4]

[b]Clinically meaningful changes were not seen in the mental health-related component score and sub-categories of Mental Health, Role Emotional, Social Functioning, and Vitality.[1]

[c]Based on a list of 29 other drugs and biologics approved with health-related quality of life data in the labeling, as of June 2012.

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.

Ask your healthcare provider if prophylaxis with ADVATE is right for you.

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ADVATE
[Antihemophilic Factor (Recombinant), Plasma/Albumin-Free Method]
Brief Summary of Prescribing Information. Please see package insert for full prescribing information.

INDICATIONS AND USAGE

Control and Prevention of Bleeding Episodes

ADVATE [Antihemophilic Factor (Recombinant), Plasma/Albumin-Free Method] is an Antihemophilic 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, paresthesias, rash, flushing, face swelling, urticaria, dyspnea, and pruritus. *[See Patient Counseling Information (17) in full prescribing information]*

ADVATE contains trace amounts of mouse immunoglobulin G (MulgG): maximum of 0.1 ng/IU ADVATE and hamster proteins: maximum of 1.5 ng/IU 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 fails to increase as expected or if bleeding is not controlled after the expected dose, suspect the presence of an inhibitor (neutralizing antibodies) 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 titer 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 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 370.5 (range: 1 to 1,256) days and the median number of exposure days to ADVATE per subject was 128.0 (range: 1 to 598).[1]

The summary of adverse reactions (ADRs) with a frequency ≥ 5% (defined as adverse events occurring within 24 hours of infusion or any event causally related occurring within study period) is shown in Table 1.

No subject was withdrawn from a study due to an ADR. There were no deaths in any of the clinical studies.

IMMUNOGENICITY

The development of Factor VIII inhibitors with the use of ADVATE was evaluated in clinical studies with pediatric PTPs (< 6 years of age with > 50 Factor VIII exposures) and PTPs (≥ 10 years of age with > 150 Factor VIII exposures). Of 198 subjects who were treated for at least 10 exposure days or on study for a minimum of 120 days, 1 adult developed a low-titer inhibitor (2.0 [BU] in the Bethesda assay) after 26 exposure days. Eight weeks later, the inhibitor was no longer detectable, and *in vivo* recovery was normal at 1 and 3 hours after infusion of another marketed recombinant Factor VIII concentrate. This single event results in a Factor VIII inhibitor frequency in PTPs of 0.51% (95% CI of 0.03 and 2.91% for the risk of any Factor VIII inhibitor development).[1,2] No Factor VIII inhibitors were detected in the 53 treated pediatric PTPs.

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 inhibitors to Factor VIII.[1] Four patients developed high titer (> 5 BU) 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.

Immunogenicity also was evaluated by measuring the development of antibodies to heterologous proteins. 182 treated subjects were assessed for anti-Chinese hamster ovary (CHO) cell protein antibodies. Of these patients, 3 showed an upward trend in antibody titer over time and 4 showed repeated but transient elevations of antibodies. 182 treated subjects were assessed for mulgG protein antibodies. Of these, 10 showed an upward trend in anti-mulgG 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
Summary of Adverse Reactions (ADRs)[a] with a Frequency ≥ 5% in 234 Treated Subjects[b]

MedDRA[c] System Organ Class	MedDRA Preferred Term	Number of ADRs	Number of Subjects	Percent of Subjects
General disorders and administration site conditions	Pyrexia	78	50	21
Nervous system disorders	Headache	104	49	21
Respiratory, thoracic and mediastinal disorders	Cough	75	44	19
Infections and infestations	Nasopharyngitis	61	40	17
Gastrointestinal disorders	Vomiting	35	27	12
Musculoskeletal and connective tissue disorders	Arthralgia	44	27	12
Injury, poisoning and procedural complications	Limb injury	55	24	10
Infections and infestations	Upper respiratory tract infection	24	20	9
Respiratory, thoracic and mediastinal disorders	Pharyngolaryngeal pain	23	20	9
Respiratory, thoracic and mediastinal disorders	Nasal congestion	24	19	8
Gastrointestinal disorders	Diarrhea	24	18	8
Gastrointestinal disorders	Nausea	21	17	8
General disorders and administration site conditions	Pain	19	17	8
Skin and subcutaneous tissue disorders	Rash	16	13	6
Infections and infestations	Ear infection	16	12	5
Injury, poisoning and procedural complications	Procedural pain	16	12	5
Respiratory, thoracic and mediastinal disorders	Rhinorrhea	15	12	5

[a] ADRs are defined as all Adverse Events that occurred (a) within 24 hours after being infused with investigational product or (b) all Adverse Events assessed related or possibly related to investigational product or (c) Adverse Events for which the investigator's or sponsor's opinion of causality was missing or indeterminate.

[b] 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.

[c] MedDRA version 8.1 was used.

Table 2
Post-Marketing Experience

Organ System [MedDRA Primary SOC]	Preferred Term
Immune system disorders	Anaphylactic reaction[a] Hypersensitivity[a]
Blood and lymphatic system disorders	Factor VIII inhibition
General disorders and administration site conditions	Injection site reaction Chills Fatigue/Malaise Chest discomfort/pain Less-than-expected therapeutic effect

[a] These reactions have been manifested by dizziness, paresthesias, rash, flushing, face swelling, urticaria, and/or pruritus.

References: 1. Shapiro A, Gruppo R, Pabinger I et al. Integrated analysis of safety and efficacy of a plasma- and albumin-free recombinant factor VIII (rAHF-PFM) from six clinical studies in patients with hemophilia A. Expert Opin Biol Ther 2009 9:273-283. **2.** Tarantino MD, Collins PW, Hay PW et al. Clinical evaluation of an advanced category antihaemophilic factor prepared using a plasma/albumin-free method: pharmacokinetics, efficacy, and safety in previously treated patients with haemophilia A. Haemophilia 2004 10:428-437.

To enroll in the confidential, industry-wide Patient Notification System, call 1-888-873-2838.

Patented under U.S. Patent Numbers: 5,733,873; 5,854,021; 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; 6,936,441; 7,094,574; 7,253,262; and 7,381,796.

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Indications and Important Safety Information

Indications

ALPROLIX, Coagulation Factor IX (Recombinant), Fc Fusion Protein, is a recombinant DNA derived, coagulation factor IX concentrate indicated in adults and children with hemophilia B for:

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

ALPROLIX is not indicated for induction of immune tolerance in patients with hemophilia B.

Important Safety Information

Do not use ALPROLIX if you are allergic to ALPROLIX or any of the other ingredients in ALPROLIX.

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 and all your medical conditions, including if you are pregnant or planning to become pregnant, are breastfeeding, or have been told you have inhibitors (antibodies) to factor IX.

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

ALPROLIX may increase the risk of formation of abnormal blood clots in your body, especially if you have risk factors for developing clots.

Common side effects of ALPROLIX include headache and abnormal sensation of the mouth. These are not all the possible side effects of ALPROLIX. Talk to your healthcare provider right away about any side effect that bothers you or does not go away, and if bleeding is not controlled using ALPROLIX.

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

Please see Brief Summary of full Prescribing Information on the next page. This information is not intended to replace discussions with your healthcare provider.

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ALPROLIX [Coagulation Factor IX (Recombinant), Fc Fusion Protein], Lyophilized Powder for Solution For Intravenous Injection.

FDA Approved Patient Information

ALPROLIX™ /all' prō liks/
[Coagulation Factor IX (Recombinant), Fc Fusion Protein]

Please read this Patient Information carefully before using ALPROLIX™ 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 ALPROLIX™?

ALPROLIX™ is an injectable medicine that is used to help control and prevent bleeding in people with hemophilia B. Hemophilia B is also called congenital Factor IX deficiency.

Your healthcare provider may give you ALPROLIX™ when you have surgery.

Who should not use ALPROLIX™?

You should not use ALPROLIX™ if you are allergic to ALPROLIX™ or any of the other ingredients in ALPROLIX™. Tell your healthcare provider if you have had an allergic reaction to any Factor IX product prior to using ALPROLIX™.

What should I tell my healthcare provider before using ALPROLIX™?

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

Tell your doctor about all of your medical conditions, including if you:

- are pregnant or planning to become pregnant. It is not known if ALPROLIX™ may harm your unborn baby.
- are breastfeeding. It is not known if ALPROLIX™ passes into breast milk or if it can harm your baby.
- have been told that you have inhibitors to Factor IX (because ALPROLIX™ may not work for you).

How should I use ALPROLIX™?

ALPROLIX™ should be administered as ordered by your healthcare provider. You should be trained on how to do infusions by your healthcare provider. Many people with hemophilia B learn to infuse their ALPROLIX™ by themselves or with the help of a family member.

See the **Instructions for Use** for directions on infusing ALPROLIX™. The steps in the **Instructions for Use** are general guidelines for using ALPROLIX™. Always follow any specific instructions from your healthcare provider. If you are unsure of the procedure, please ask your healthcare provider. Do not use ALPROLIX™ as a continuous intravenous infusion.

Contact your healthcare provider immediately if bleeding is not controlled after using ALPROLIX™.

What are the possible side effects of ALPROLIX™?

Common side effects of ALPROLIX™ include headache and abnormal sensation in the mouth.

Allergic reactions may occur. Call your healthcare provider or get emergency treatment right away if you have any of the following symptoms: hives, chest tightness, wheezing, difficulty breathing, or swelling of the face.

ALPROLIX™ may increase the risk of forming abnormal blood clots in your body, especially if you have risk factors for developing blood clots.

Your body can also make antibodies called, "inhibitors," against ALPROLIX™, which may stop ALPROLIX™ from working properly. Your healthcare provider may need to test your blood for inhibitors from time to time.

These are not all the possible side effects of ALPROLIX™.

Talk to your healthcare provider about any side effect that bothers you or that does not go away.

How should I store ALPROLIX™?

Store ALPROLIX™ vials at 2°C to 8°C (36°F to 46°F). Do not freeze.

ALPROLIX™ vials may also be stored at room temperature up to 30°C (86°F) for a single 6 month period.

If you choose to store ALPROLIX™ at room temperature:

- Note on the carton the date on which the product was 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 product or diluent after the expiration date printed on the carton, vial or syringe.

After Reconstitution:

- Use the reconstituted product as soon as possible; however, you may store the reconstituted product at room temperature up to 30°C (86°F) for up to 3 hours. Protect the reconstituted product from direct sunlight. Discard any product not used within 3 hours after reconstitution.
- Do not use ALPROLIX™ if the reconstituted solution is cloudy, contains particles or is not colorless.

What else should I know about ALPROLIX™?

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

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