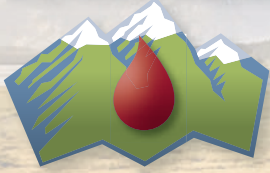


THE ROCKY MOUNTAIN

Rocky Mountain Hemophilia



& Bleeding Disorders Association



RMHBDA is a 501(c)(3) nonprofit organization founded in 2000 and is a chartered chapter of the National Hemophilia Foundation.

Our mission is to improve the quality of care and life for persons with inherited bleeding disorders, including hemophilia and von Willebrand Disease through education, peer support, resources, and referral.

In This Issue

- Family Camp 2015 1
- RMHBDA Education Weekend 2015 1
- 2014 Walk for Hemophilia Was Great! 1
- Have You Noticed More Ads? 1
- Walk Photos 2
- NHF Conference Recap 6
- 2014 Mile High Colorado Camp 7
- Men's Retreat 2015 7

Rocky Mountain Hemophilia & Bleeding Disorders Association

2100 Fairway Drive, Suite 107
Bozeman, Montana 59715-5815
406.586.4050

www.rmhbda.org

Brad Benne, Executive Director

brad@rmhbda.org



www.facebook.com/rmhbd

Family Camp 2015

June 19 – 21

Fairmont Hot Springs, Anaconda, Montana

For more information, visit www.fairmontmontana.com



Each summer, RMHBDA invites affected families living in Montana and Wyoming to attend a weekend retreat. The weekend is packed full of education, bonding, and fun!

For the parents and teens, we will have teambuilding programming led by our guest, hemophilia leadership expert, Pat Torrey and some time to relax with other families. This is a great opportunity to learn from and share experiences with one another.

We also have many great activities planned for our campers including arts & crafts projects, field games, and educational sessions for children with bleeding disorders and their siblings. Infusion classes will be offered from our HTC.

Call Brad with any questions at 406.586.4050

Have You Noticed More Ads?

Most of the time, most of us ignore ads and/or find them an irritating intrusion. However, with nonprofits in general, and especially as a nonprofit for a health issue as significant as hemophilia and other blood disorders, our advertisers are our sponsors and supporters in so many ways. These companies are creating longer lasting drugs, and cutting edge research such as gene therapy could be a game changer for families dealing with bleeding disorders. They also provide substantial support to RMHBDA for our events, our newsletter, and more, helping our community in substantial ways.

It's an exciting time for our community regarding medical research and the development of better medicines. So take the time to read the ads and make note of the companies that actively support us. And if you have the opportunity to meet one of their reps, share your appreciation for their support of RMHBDA!



RMHBDA Education Weekend 2015

February 27 – March 1

Our Education Weekend will take place at the Hilton Garden Inn, Bozeman, Montana.

We need help organizing! Please contact Brad at 406.586.4050 if you are interested in serving on the Education Weekend committee — this is **your** organization!

2014 Walk for Hemophilia Was Great!

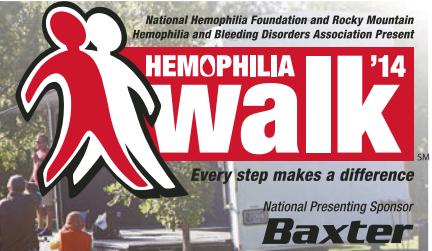
Thank you for joining us for our 3rd annual Walk to support our chapter and families dealing with bleeding disorders in Montana & Wyoming. We had over 200 walkers at Zoo Montana in Billings, Montana. Good natured and generous supporters helped raise over \$55,000 and awareness. I want to send a very gracious thank you to our volunteers, team captains, and walkers for making our walk a tremendous success. We are so grateful for your participation.

We would also like to extend a very gracious thank you to our local and corporate sponsors: St. Vincent's Healthcare, Barnard Construction, Baxter, Bayer, Biogen Idec, Bozeman Deaconess, Avitus Group, Fifth Street Design, First Interstate Bank, Grifols, HF Healthcare, Accredo, Walgreens, Octapharma, Fuller Family Medicine, Novo Nordisk, Pfizer, CVS Caremark, and Restore RX.

Sincerely,
Brad Benne, Executive Director



Congratulations On A Successful Walk!



Walk Photos

The Third Annual RMHBDA Walk was a remarkable success raising over \$55,000 and raising awareness of RMHBDA and of blood disorders and safety to the public. It was also wonderful fun with a great turnout as you can see on these pictures.

We also wish to honor and thank our top fundraisers and teams!

Top Fundraisers

John & Will Benne – \$4,410	Jessica Amende – \$535	John & Will Benne – \$400
Campbell Hunter – \$2,810	Jaxon Stafford – \$521.32	Forrest Berg – \$290
Kristal Graham – \$1,994	Kelly Coleman – \$500	Jane Robertson – \$250
Dylan Hunter – \$1,620	Chris Graham – \$475	Anessa Woolford – \$250
Lisa Maxwell – \$1,125	Connor Ferriter – \$430	Silent Donor – \$225
Jodi Rudell – \$778	3 BROTHERS from Montana – \$400	Chris Hunter – \$220
Ty Graham – \$690	Brian, Marie, & Ethan Frame – \$400	

Top Teams

Ty's Crew 2 – \$12,495	The VW Ladybugs Plus One – \$978	Walgreens Infusion Services – \$75
Blood Brothers III – \$7,090	Connor's Comrades – \$555	Simply Family Magazine – \$75
The Warriors – \$5,540	Clot Like an Amende – \$535	Blue Moon Pride – \$50
Best of the Bleed – \$2,387.40	Wyo Red's – \$531.32	Bleedership Brotherhood – \$25
Bountiful Blood Seekers – \$1,675	3 Brothers from Montana – \$450	Arrowhead – \$10
St. Vincent Healthcare – \$1,266	Carter Carriers – \$250	RMHBDA Dream Team – \$8
MAX OUT – \$1,150	Biogen Idec – \$100	



www.facebook.com/rmhbd



Luis Estrada had a rough start in life. As a toddler in Costa Rica, Luis fell and became paralyzed from his chest down to his feet. A few months earlier, his father had died in a car accident, forcing his mother to work full-time away from home to support Luis and his two sisters.

“My friends would get me to and from school, and play with me in the sugar cane fields,” Luis recalls. “I had support from good people.”

Doctors diagnosed Luis with severe hemophilia A shortly after his birth. In the late 1950s and early 1960s in Costa Rica, blood transfusions were his only treatment.

His family inspired him to be responsible and self-reliant. “A cousin would tell me that I wasn’t disabled, that I could help to do the chores around the house, so I learned to do things for myself, like cooking, cleaning, and sewing.”

Despite his challenges, Luis says he had a great childhood. “When I was about seven or eight, I’d play goalie during easy soccer games with my friends. I was pretty good in my wheelchair,” he remembers fondly.

Luis and his family moved to San Francisco when he was a teenager. Like most teenagers, Luis wanted to be as active and mobile as possible.

“When I had bleeds in my left shoulder and elbow, I’d start using my right arm so I could keep moving,” explains Luis. “Eventually my right shoulder and elbow would bleed, so I’d switch back to using my left arm. Then those joints would bleed again. It got so bad that I was going to the hospital just about every week. Sometimes I’d be admitted for a few days, other times for a week or two.”

Luis has been married to his wife, Laura, since 2000. She will never forget Luis’ frequent hospital stays. “It was horrible to see him in pain,” Laura recalls. “I was frustrated and angry because I couldn’t help him, but I had to suppress my feelings. It was exhausting.”

“Laura was always supporting me, forcing me to go to the hospital even when I didn’t want to,” Luis says. “I knew it was very hard for her to see me so uncomfortable.”

You should not use ADVATE [Antihemophilic Factor (Recombinant)] if you:

- Are allergic to mice or hamsters.
- Are allergic to any ingredients in ADVATE.

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

.....
.....
.....



“Before I started infusing prophylactically, my annual bleed rate was over 50. Now my ABR is down to five or six...”

—

Luis’ doctor eventually prescribed a prophylaxis regimen with ADVATE [Antihemophilic Factor (Recombinant)], a medicine used to replace clotting factor VIII that is missing in people with hemophilia A. It can reduce the number of bleeding episodes in adults and children (0-16 years) when used regularly (prophylaxis). Luis infuses every other day.

You can hear the gratitude in Luis’ voice. “Before I started infusing prophylactically, my annual bleed rate was over 50. Now my ABR is down to five or six.”

“Now I have more time for myself. I go out with friends for coffee or lunch. I’m doing yoga and studying for my degree in art and sociology.”

Luis and Laura love to travel together. They have visited cities across the U.S., and have made several trips to Costa Rica to visit their families. Luis has also returned to a favorite activity of his youth. “I love kicking around a soccer ball with my four-year-old nephew. He likes when I play goalie, just as I did when I was only a few years older than he is now.”

According to Laura, “They love each other, they’re good for each other and they definitely help each other.”



ADVATE Prophylaxis May Help You Prevent or Reduce Bleeds¹

Significant reduction in median annual bleed rate (ABR) with prophylactic treatment compared with on-demand treatment¹

.....
.....
.....
.....
.....
.....
.....

INDICATIONS

ADVATE 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.

DETAILED IMPORTANT RISK INFORMATION

You should not use ADVATE if you:

- Are allergic to mice or hamsters.
- Are allergic to any ingredients in ADVATE.

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

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, sweating, 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.



.....
.....
.....
.....
.....
.....

ADVATE [Antihemophilic Factor (Recombinant)] is a recombinant antihemophilic 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.

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

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 (MulgG) ≤ 0.1 ng/IU ADVATE, and hamster proteins ≤ 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 (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 •••••]

- 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 •••••]
- 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.

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 $\geq 10\%$ of subjects) were pyrexia, headache, cough, nasopharyngitis, vomiting, arthralgia, and limb injury.

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 $\leq 2\%$ 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 (range: 1 to 598).³

The summary of adverse reactions with a frequency $\geq 5\%$ (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.

≥

Adverse Reaction	PTPs (n=228)	PUPs (n=6)	Total (n=234)
Pyrexia	•••••	••	•••••
Headache	•••••	••	•••••
Cough	•••••	••	•••••
Nasopharyngitis	•••••	••	•••••
Vomiting	•••••	••	•••••
Arthralgia	•••••	••	•••••
Limb injury	•••••	••	•••••

Adverse Reaction	PTPs (n=228)	PUPs (n=6)	Total (n=234)
Factor VIII inhibition	•••••	••	•••••
Injection site reaction	•••••	••	•••••
Chills	•••••	••	•••••
Fatigue/Malaise	•••••	••	•••••
Chest discomfort/pain	•••••	••	•••••
Less-than-expected therapeutic effect	•••••	••	•••••

³ Adverse reactions 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.

⁴ The ADVATE clinical program included 234 treated subjects from 5 completed studies in PTPs and 1 ongoing trial in PUPs as of 27 March 2006.

⁵ MedDRA version 8.1 was used.

The development of factor VIII inhibitors with the use of ADVATE was evaluated in clinical trials 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 BU in the Bethesda assay) after 26 exposure days. Eight weeks later, the inhibitor was no longer detectable, and 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).^{3,4} No factor VIII inhibitors were detected in the 53 treated pediatric PTPs. In clinical trials 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.³ Four subjects 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 subjects, 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 (WVF) antibodies, none displayed laboratory evidence indicative of a positive serologic response. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to ADVATE with the incidence of antibodies to other products may be misleading.

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.

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.

Baxter, and Advate are trademarks of Baxter International Inc. Baxter and Advate are registered in the U.S. Patent and Trademark Office.

Patented: see www.baxter.com/productpatents/

Westlake Village, CA 91362 USA

U.S. License No. 140 Issued 04/2014
USBS/34/14-0104

Baxter

.....

NHF Conference Recap

Washington, D.C.

We had one of our largest group's from RMHBDA attend the National Hemophilia Foundation's Annual Meeting this year in Washington D.C. The Hart/Cohenour Family, the Rudell Family, Lisa Maxwell, and Brad Benne. We would like to thank the Colburn Keenan Foundation for providing generous support to our chapter enabling us to send more families to the conference this year!

One of our young participant's said, "I love coming to these conferences and learning new things. I learn something new at ever conference I attend". The opportunity to attend the NHF annual conference provides incredible tools for families coping with bleeding disorders including networking, educational and beneficial sessions, and even some good family time.

Please contact Brad Benne if you are interested in attending the NHF Annual Conference in Dallas, Texas in August of 2015.



2014 Mile High Colorado Camp

An Empowering Experience

Mile High camp was a huge success again this year, nearly a hundred children from Colorado, Montana, and Wyoming attended camp this year. A special "Thank You" to our University of Colorado Hemophilia Treat center for sponsoring Mile High Camp. The opportunity each camper encounters is empowering and life-changing. I want every kid dealing with bleeding disorders in Montana and Wyoming to experience Mile High Camp. Stay tuned for information about next year's camp in March of 2015!



Men's Retreat 2015

January 9 – 11, 2015
Friday – Sunday
West Yellowstone, Montana

Please contact Brad if you are interested in attending and/or planning our Men's retreat. Our retreat includes a snowmobile trip into Yellowstone National Park. All of your expenses to attend can be covered by RMHBDA, including fuel assistance.

Please RSVP to Brad at 406.586.4050 or brad@rmhbda.org.

Twice the factor*



Alphanate[®]
Antihemophilic Factor/von Willebrand
Factor Complex (Human)





HI HLI HTS F PR SCRIBIN INF R ATI N

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

ALPHANAT (ANTIHEMOPHILIC FACTOR) INJECTABLE SOLUTION
FACT R C PL HU AN)

Sterile, lyophilized powder for injection.

Initial U.S. Approval: 1978

INDICATIONS AND USAGE

Control and prevention of bleeding episodes in patients with hemophilia A and von Willebrand Disease: Surgical and/or invasive procedure in adult and pediatric patients except Type 3 undergoing major surgery.

ADMINISTRATION AND DOSAGE

For Intravenous use only.

Control and prevention of bleeding episodes in patients with hemophilia A: Control and prevention of bleeding episodes

Hemophilia A: Control and prevention of bleeding episodes

Control and prevention of bleeding episodes in patients with hemophilia A: Control and prevention of bleeding episodes

von Willebrand Disease: Surgical and/or invasive procedure in adult and pediatric patients except Type 3 undergoing major surgery

Control and prevention of bleeding episodes in patients with hemophilia A: Control and prevention of bleeding episodes

Control and prevention of bleeding episodes in patients with hemophilia A: Control and prevention of bleeding episodes

ADVERSE REACTIONS AND CONTRAINDICATIONS

Adverse reactions and contraindications for Alphanate.

CONTRAINDICATIONS

Contraindications for Alphanate.

WARNINGS AND PRECAUTIONS

Warnings and precautions for Alphanate.

Warnings and precautions for Alphanate.

Warnings and precautions for Alphanate.

Warnings and precautions for Alphanate.

Warnings and precautions for Alphanate.

Warnings and precautions for Alphanate.

Warnings and precautions for Alphanate.

ADVERSE REACTIONS

Adverse reactions for Alphanate.

To report SUSPECTED ADVERSE REACTIONS, contact Grifols Biologicals Inc. at 1-888-GRIFOLS (1-888-474-3657) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

US PATENT INFORMATION

US Patent information for Alphanate.

GRIFOLS

Grifols Biologicals Inc.

Grifols Biologicals Inc.

 **ALPROLIX™**
[Coagulation Factor IX
(Recombinant), Fc Fusion Protein]

Now Available

A new treatment for hemophilia B

ALPROLIX provides protection* from bleeds starting with at least a week between prophylaxis infusions.

Dosing regimen can be adjusted based on individual response.

*Protection is the prevention of bleeding episodes using a prophylaxis regimen.



To learn more, contact CoRe Manager **Becky Ybarra**
E: becky.ybarra@biogenidec.com T: 801.913.8204

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.**

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.

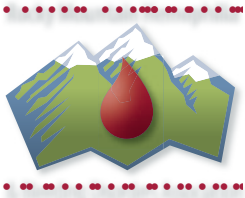
After Reconstitution:

- 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.

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



2100 Fairway Drive, Suite 107
Bozeman, Montana 59715-5815

FALL 2014

Address Correction Requested

Non Profit Org.
US Postage

Bozeman, MT 59718
Permit No. 209



As the industry leader in coagulation therapies, CSL Behring offers the most extensive portfolio of coagulation products for patients with factor deficiencies, including F1, FVIII, FIX, FXIII, and von Willebrand factor. And we continue to broaden our efforts with a number of recombinant factor therapies in development, including rFVIII, rFVIIa, rFIX, and rVWF.

For more information about our factor products for hemophilia, von Willebrand disease, and other rare bleeding disorders, or to learn about our innovative patient programs, please visit www.cslbehring.com or call consumer affairs at 1-888-508-6978.

CSL Behring
Biotherapies for Life™