the artery

Serving Michigan's bleeding disorders community

Winter 2020/2021

EAGLE JOURNEYS
CAMPING PROGRAMS

HFM's Eagle Journeys exists to educate and empower kids with bleeding disorders to live a life of freedom and independence

hfm©

HFM exists to enhance the quality of life for all affected by bleeding disorders

There were so many ways to participate in 2020

INSIDE THIS ISSUE

Susan Fenters Lerch

We are here for you.

"Together we can face any challenges as deep as the ocean and as high as the sky."
~Sonia Gandhi

Dear HFM family and friends,

This is an extraordinary year to consider as we have each faced a variety of hardships and challenges. We've needed to figure out how to best reach out, and further understand our bleeding disorder community's needs and resilience.

My hope is that today and as we go forward, you remain safe and hopeful.

We have considered the pros and cons of various online programming, experimenting and learning from various methods on how to best offer opportunities to connect in new and varied formats. Of course, this has not been simple. I am immensely proud of HFM's staff team, leadership volunteers, community members, and healthcare providers who have contributed to meaningful engagement with one another and for our constituency. As always during a crisis, there have been silver linings. We've heard from people who had not participated with in-person gatherings for any number of reasons, who have found online programming an improved way to connect and receive information and education.

We understand, of course, many of you want to return to connecting in person – we miss smiles, hugs, impromptu conversations.

At this point, with the advice and support of NHF, as well as physician consultants, we expect HFM programming will remain virtual through June of 2021. We remain optimistic about the new year, yet we want to be able to offer safe, well-planned education and connection within our community.

I understand this is tough, we have felt an acute loss of connection in 2020. Once we are able to get together it is likely going to take time to readjust while determining how best to move forward. **We will continue to seek the advice** of medical professionals as well as listening to our own comfort level and expectations for participation as we consider the best and safest ways to provide education in 2021.

For many, this year has further demonstrated what is most important in our lives. I lost my mom recently, which was so difficult and unexpected. My dear friend, colleague, and community member, **Shari Luckey**, lost her mom as well. Our hearts are broken; we know many others have also lost loved ones. I am grateful to see all the ways the bleeding disorders community supports one another. There is goodness all around us.

My hope is we will continue forward with optimism to offer and provide services and support including the essential characteristics of goodwill, generosity, and grace to one another in the New Year.

I wish you and yours light and love!

Susan Fenters Lerch
HFM Executive Director
Federal Great Lakes Region – V-E HTC Network Director

Honoring Alice & Linn,
and sending love to my friend Shari.

Me, with my beloved mom, **Alice Peterson** (4/7/1935-10/5/2020). An HFM supporter since the 1980s.

Shari, with her beloved mom, **Linn Wilson** (7/7/1946-10/19/2020). Lifelong supporter & community member.

We Couldn't Do It - and We Don't Want to Do It - Without You!

Gwyn Hulswit

Like for all of you, 2020 has been a year of challenge, growth, and opportunity at the Hemophilia Foundation of Michigan (HFM). At the beginning of the COVID-19 pandemic we reached out to you, our community, to ask how we could best support you and your family. Through a written community assessment and in sharing your thoughts with us on social media and phone calls, you told us how important it is to continue to connect, learn, and come together in joyful ways – and we are happy that we were able to provide ways to connect online throughout the year.

How did you participate with the HFM community this year? Perhaps you joined us for a Wednesday dinner talk program and learned tips to avoid caregiver burnout, or learned something new about the potential of gene therapy, or learned how to bring more laughter into your life. Or perhaps your child received an enormous (seriously, like the size of the Michigan Big House enormous!) box of activity supplies that included everything necessary for four weeks of HFM's virtual camp programing. Or maybe you connected with others across the state during one of our virtual retreat weekends or community nights, or across the country during our National Conference for Women with Hemophilia, making new friends and learning more about resources to help you and your family.

These new and continued programs are not possible without you. Your attendance, your support, and your financial gifts allow us to make our entire community stronger. Despite COVID-19 we have experienced new ways of coming together, seeing those of you who haven't participated before due to the inconvenience of traveling for in-person events, and creating tighter connections as we spend more time reaching out and checking in with one another.

Now, more than ever, is the time to show one another care and support. If you have joined us this year, we are so glad you did. If you thought about joining yet weren't able to "zoom" with us this year, we welcome you with open arms to participate in our 2021 programming. To ensure HFM's continued mission to provide education and support, we hope you all will consider an end of the year gift. You can make a gift by using the envelope in this newsletter (if you have a hard copy in your hands) or by going to **www.hfmich.org/donate**.

Thank you for all that you do – for yourself, for your family, for your HFM community. Your support ensures our continued work to support, engage, and bring joy to the bleeding disorders community. Your gifts make a difference. YOU make a difference, especially now. Thank you.

Your support provides hope and connections when our community needs it most! www.hfmich.org/donate

Amazon Gives Back Through their Amazon Smile Program

Amazon Smile provides donations to HFM from the purchases made by our community. If you have an Amazon Prime account, or are purchasing items from Amazon, your purchases can generate donations at no additional cost to you. **Simply log in to www.smile.amazon.com when placing an order.** The first time you login using your established amazon credentials, you will be asked to select your charity. Please pick The Hemophilia Foundation of Michigan. It's as easy as that.

In the last five years HFM has received over $1,500 from Amazon. Join us in making your purchases through Amazon Smile and help HFM continue to provide meaningful programs and services to the Michigan bleeding disorders community.

A Glimpse at our Conference

Creating Change – Policy, Practices, and Programs*
Panelists: Meera Chitlur, MD; Kerry Funkhouser, EdD; Ann-Marie Nazzaro, PhD; Len Valentino, MD

Care in the Time of COVID-19
Facilitated by mental health professionals: Angela Beebe, BHS; Karen Boyd, LMSW, ACSW, DCSW; Lisa Clothier, LMSW, ACSW; Mina Ngyuen-Driver, PsyD; Annie Phillips, LMSW; Dave Rushlow, LMSW

Managing a High Risk Pregnancy*
Meera Chitlur, MD

Coping with Anxiety and Depression
Cathy Tiggs, MSSA, MSSA, LISW
sponsored by Novo Nordisk

Getting What You Need: Sexuality and Chronic Conditions
Sarah Watson, LPC, CST, ATR, Certified Sex Therapist

Keeping Healthy While Aging
Laura Gusba, CNP

Mythbusters!
Jennifer Maahs, MSN, PNP, RN-BC

Make Your Case: How Hemophilia Does Not Just Affect Men
Shelley Gerson, MEd, Community Relations and Education Manager, Sanofi Genzyme

Diagnosis and Treatment of Women with Hemophilia over the Lifespan*
Robert Sidonio, MD

CDC Community Counts Bleeding Disorders Surveillance – a resource for women with hemophilia*
Vanessa R. Byams, DrPH, MPH

Research to Better Understand Factor Levels & Bleeding in Carriers*
Jill Johnsen, MD

Anemia and Iron Supplements*
Jim Munn, MS, BS, BSN, RN-BC

Yoga for Every Body
Sherry Herman-Hilker, PT, MS;
Sarah Procario, RYT 200

Parenting School Aged Children in the Time of COVID-19
Mina Nguyen-Driver, PsyD

Challenges for Teen Girls with Hemophilia
Cindy Sabo, MSN, RN, CNP;
Laura Gusba, CNP

Genentech's Commitment to Hemophilia A
Ami Seligman, RN, Genentech Nurse Educator

Planning Your Future: Aging with Hemophilia
Rachel Cooper-Leal, Sr. Manager, Patient Affairs, Pfizer

***Traducido al español**

2020 National Conference for Women & Teens with Hemophilia

Hear Our Voices: Continuing to Thrive

Presented virtually October 9–10, 2020
3–8pm EST both days

HFM was pleased to sponsor the 3rd Annual National Conference for Women and Teens with Hemophilia, which took place virtually from Friday, October 9 and Saturday, October 10, 2020. One hundred and twenty-three women and teens with hemophilia registered, representing thirty-five states and six international locations.

Over the two-day conference, 338 participants joined, 198 on October 9 and 140 on October 10, to hear from national experts on bleeding disorders and to share questions, challenges, and triumphs, and to discuss action steps and ways in which women with hemophilia can be better supported through testing, diagnosis, and treatment. Participants each day included women and teens with hemophilia as well as hemophilia treatment center staff from across the country.

Throughout the conference, women were encouraged to share their experiences and to respond to various poll questions. The data collected emphasize the impact of this conference. Ninety-six percent indicated that as a result of this conference that they would take specific and measurable action steps related to their health and their bleeding disorder in the next year.

When asked what they would do, the women responded in the following manner:

WHAT WILL YOU DO DIFFERENTLY?	PERCENTAGE
Increase Advocacy	65%
Improve Physical Health	22%
Focus on Mental Health	16%
Request Testing	15%
Log/Track Bleeds/Symptoms	11%
Improve Contact with Hematologist	9%
Other	7%
Please note attendees could choose multiple categories	*Percentages will not equal 100%*

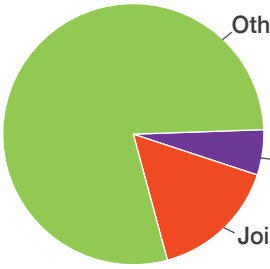
Many women added to the above information with statements about their future plans:

- I will continue to advocate for myself and not back down in the face of medical professionals who try to discredit me.
- I will be documenting more, speaking up more, and pushing my care providers to look at how my various comorbidities affect each other and my health. Right now, I am seen as too complex to understand. I would like the focus to be more on treating the problem rather than only the symptom. Every year this conference has sent me home with knowledge that helps me get that message to my doctors. It is slow, but my care is changing.
- I realized I have an annual bleed rate of 36 bleeds. I have never before actually realized that. I will fight harder for prophy.
- After the conference I contacted my hematologist. I hadn't seen him in 2 years. I find that I don't stay up on my health care needs. I will do better this year.
- I'm developing arthritis in my hands (already have it on my knees) and I don't want it to get worse in a rapid manner so I want to talk to my doctor about getting prophylaxis treatment.
- I will keep my appointments that are needed. Get my daughters to understand it is important for them to follow up with their appointments.

Life changing! This conference gave me a voice and brought amazing women into my life! It changed everything. ~ 2020 Attendee

As treatment for their hemophilia is an important topic during the conference, one of the questions posed to the women asked about their experience being prescribed factor product for different needs. For those who indicated that they were prescribed factor for reasons other than menstrual bleeding or joint bleeding the most common other responses indicated situations related to surgery as well as on demand needs.

If you have ever been prescribed factor, what were your symptoms?



***Common answers to other:**
- Surgery
- Never prescribed factor
- Spontaneous or on demand

As women shared and discussed their experiences and plans during the conference, they also expressed what this conference meant to them. As HFM looks forward to making plans for 2021, it is remarkable to note how many steps have been made to recognize, support, and treat women with hemophilia as a result of this conference. We are grateful for our speakers, sponsors, and of course, every single attendee!

Attendees also shared:

- I would tell a friend that my experience was great. Even after being in the bleeding disorders community all my life, (brothers, children, and self with factor IX hemophilia), I came away with tangible, useful knowledge that I have already incorporated into my life.
- It was a very positive, uplifting, and validating experience!
- This conference is always a wonderful, empowering time when women and medical/hemophilia professionals connect. The information is invaluable. Many have walked away and greatly improved their healthcare plans.
- I loved the whole event and what comes with it. In a world where hemophilia in women is such a new concept it's wonderful to feel validated and be seen. I know and understand that life is hard for everybody but you don't know what it is to raise a kid with hemophilia and then when you are 50 to find that you are also affected by the condition!

Attendees for HFM's 2020 National Conference for Women and Teens with Hemophilia are from:

Arizona, Arkansas, California, Colorado, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Virginia, and Washington

Participation outside the 50 US States:

Corozal, Puerto Rico
Ontario, Canada
Telangana, India
Tehran, Iran
Australia
New Zealand

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Special Considerations for Girls

The Onset of Menstruation May Be a Time to Focus on a Hemophilia Care Plan

For more information, visit b2byourvoice.com to download *Hemophilia B: Her Voice, Her Life.*

Puberty on its own can be a difficult experience, but it can become even more complicated with a hemophilia diagnosis. The start of menstruation is one of the many aspects of a girl's life that may be affected by a bleeding disorder. For girls who are showing symptoms of hemophilia, puberty may be a good time to identify a health care team and develop a care plan.

Identifying a Health Care Team

The lack of knowledge about how hemophilia impacts girls can affect the level of medical care and emotional support received by a girl with this condition.[1] It may be recommended that a girl who is diagnosed with hemophilia wear a medical identifier at all times so that medical personnel are aware of her bleeding disorder in an emergency. It is important for every female with hemophilia to enlist a team that includes a primary care physician, a gynecologist, and a hematologist who can coordinate care and needs.[2]

Tools that can help girls manage symptoms include[3]:

- Care plans designed for patients by their team of health care providers to help facilitate care coordination
- Apps that allow patients to track their hemophilia symptoms and care
- Self-monitoring assistance for better symptom accuracy

Heavy Menstrual Bleeding

Periods with heavy blood loss (called *menorrhagia*) can lead to anemia and have a negative effect on quality of life. Girls with bleeding disorders who are experiencing symptoms of menorrhagia should have a discussion with their health care team in order to coordinate management and care.[4]

The signs and symptoms of menorrhagia include[4]:

- Having a menstrual period that lasts longer than 7 days
- Needing to change pads or tampons at least every 2 hours
- Passing blood clots larger than a quarter
- Bleeding that affects daily activities

"I am a true testament to the fact that factor replacement therapies can help when it comes to being a woman with hemophilia. Not only do we have to deal with the joint bleeds that men do, but we also have specific issues as women."

- ELIZABETH
Has hemophilia B

Tips for Parents[4]

Parents of a girl with a bleeding disorder can ease their daughter's transition into puberty by preparing her for the experience of having periods and helping her learn how to manage them. It can also be helpful for parents to ensure that a supply of feminine products is available and provide a way for their daughter to carry the products discreetly if needed. Parents can also help by providing honest, accurate information about menstruation and the impact hemophilia may have.

The beginning of menstruation, which can already be a confusing and demanding time in the life of any girl, brings special concerns for those showing symptoms of hemophilia. It's important for girls to talk with health care providers and caregivers about their periods, especially if bleeding becomes heavy.

References: 1. Aldridge S. The carrier barrier: women push for mild hemophilia diagnosis. HemAware.org Web site. www.hemaware.org/story/carrier-barrier. Published July 19, 2012. Accessed February 20, 2019. **2.** Canadian Hemophilia Society (CHS). Precautions for pregnant women with a bleeding disorder. Hemophilia.ca Web site. www.hemophilia.ca/en/women/precautions-for-pregnant-women/. Accessed February 20, 2019. **3.** Carr S. A new look at patient communications in outcomes-driven healthcare. Pharmaphorum.com Web site. http://pharmaphorum.com/views-and-analysis/a_new_look_at_patient_communications_in_outcomes-driven_healthcare/. Published November 5, 2012. Accessed February 20, 2019. **4.** National Hemophilia Foundation (NHF). Effects of puberty on girls with a bleeding disorder. StepsforLiving.Hemophilia.org Web site. https://stepsforliving.hemophilia.org/next-step/maintaining-a-healthy-body/growing-up-puberty/effects-of-puberty-on-girls-with-a-bleeding-disorder. Accessed February 20, 2019.

PATIENT AFFAIRS LIAISONS

Patient Affairs Liaisons are Pfizer hemophilia employees who are dedicated solely to providing support to the community. Your Pfizer Patient Affairs Liaison is available to help you access the support and information you need. To find your Patient Affairs Liaison, go to hemophiliavillage.com/support/patient-affairs-liaison-finder or call Pfizer Hemophilia Connect® at 1.844.989.HEMO (4366).

PP-HEM-USA-1168

April 2019

Pfizer


Angela Beebe


Patrice Thomas


Sarah Procario


Tim Wicks

Let Their Voices be Heard

Angela Beebe

The 2020 National Conference for Women and Teens with Hemophilia marks three years of women with hemophilia coming together to celebrate the strength of sisterhood. I was honored to join the conference this year as a speaker for these women who motivate me to stand a little taller, speak a little louder, and strive for equality. Over the two-day conference, I was impacted by the stories of the women and the barriers they have had to overcome–and though there remain barriers to break I have no doubt they will continue to persevere. HFM is pleased to be a part of their journey.

I interviewed a few members of the HFM staff on their experience planning and hosting this year's virtual conference.

Patrice Thomas, MS, MSW

Patrice Thomas, Director of Program Services at HFM, has organized the National Conference for Women and Teens with Hemophilia since its inception in 2018 with help and support from HFM staff, conference participants, and other leaders in the bleeding disorders field. During our interview, Patrice shared that she was impressed by the main stage and all the fabulous speakers. The knowledge and information provided by the speakers is just fuel to the advocacy work the women are doing for themselves every day. Patrice also shared how different this year felt without the physical in-person connection, yet stressed the value of this virtual experience. Patrice is guided by the belief that HFM's National Conference for Women and Teens with Hemophilia programming should help women achieve their goals.

Sarah Procario, RYT 200

Sarah Procario, Advocacy Director and Communications Manager at HFM, participated in the conference both as HFM staff and as a presenter. Sarah is known for her talent to teach yoga in an inviting way that allows for modifications. It was clear during the conference that women appreciate and value Sarah–her calming voice, her ability to modify yoga for women with hemophilia, and her warm presence. During Sarah's interview, she expressed her passion for yoga and her desire to introduce yoga as a mind-body practice that can be accessible to all regardless of size, age, or physical limitations due to one's experience with hemophilia. Sarah and her yoga are a conference staple. During Sarah's interview, she reflected on how much the women want to be at the conference and how that makes everything worthwhile and a truly momentous experience.

Tim Wicks

Tim Wicks, Camp Director/Youth Services Manager at HFM, provided his insight about the 2020 National Conference for Women and Teens with Hemophilia. Tim started his interview joking about the fact this year's AV set up was much easier on him physically by sharing, "I was able to sit back in my chair." All jokes aside Tim did amazing work in the background to make the conference run as smoothly as possible. Tim talked about how this year's experience motivated him to want to have a hybrid approach moving forward to ensure that every woman had access in the future. During Tim's interview, he explained how eye-opening the conference has been for him over the past three years. Tim shared his experience growing up watching the effects of hemophilia on his mother and sisters. After attending the conference for the past three years he feels strongly that the idea of "just a carrier" needs to be dissolved. He has been able to see hemophilia through the eyes of the women and is dedicated to changing the understanding of who has hemophilia. As an individual with hemophilia himself, Tim knows the importance of treatment and is hopeful to see women receive the care they need. Tim believes HFM's 2020 National Conference for Women and Teens with Hemophilia is part of the path towards equal treatment.

Final Thoughts

HFM's staff is dedicated to HFM's National Conference for Women and Teens with Hemophilia and it is clear each staff member is passionate about ensuring the voices of the women are heard. This year may have looked a bit different but that did not limit participants' voices. HFM remains committed to supporting women with hemophilia in sharing their voice and reshaping the understanding of who has hemophilia. I invite everyone in the bleeding disorders community to talk to women with hemophilia and hear their stories. I was honored to be part of the 2020 National Conference for Women and Teens with Hemophilia–thank you to every one of the women who shared their story and continue to let their voices be heard.

In a year filled with so much uncertainty, I am grateful for all the ways HFM has created opportunities for me to connect, learn, and feel supported! ~ Community member, 2020

PAID CONSUMER OUTREACH

No actual patients depicted.

ADYNOVATE
[Antihemophilic Factor (Recombinant), PEGylated]

REAL LIFE. REAL BLEED PROTECTION.*

AdynovateRealLife.com

HEMOPHILIA A IS A PIECE OF YOU.

NOT ALL OF YOU.

ADYNOVATE® is a treatment that can be personalized to fit your lifestyle so you have more time to spend doing the other things that also make you, you. It has a simple, twice-weekly dosing schedule on the same 2 days every week.[1,2]

*In clinical trials, ADYNOVATE demonstrated the ability to help prevent bleeding episodes using a prophylaxis regimen.

ADYNOVATE twice-weekly prophylaxis prevented or reduced the number of bleeds[2]

ADYNOVATE was proven in 2 pivotal clinical trials to prevent or reduce the number of bleeding episodes in children and adults when used regularly (prophylaxis)[2]

- **Children Under 12 Years**: This study evaluated the efficacy of ADYNOVATE twice-weekly prophylaxis and determined the ability to treat bleeding episodes for 6 months in 66 children under 12 years old who received 40–60 IU/kg of ADYNOVATE prophylaxis treatment[2]
  - During the 6-month study in children under 12, those receiving twice-weekly prophylaxis treatment experienced a median† overall ABR‡ of 2.0
  - 0 bleeds in 38% (25 out of 66 patients) during 6 months on twice-weekly prophylaxis
- **Adolescents and Adults 12 Years and Older**: This study evaluated the efficacy of ADYNOVATE in a 6-month study that compared the efficacy of a twice-weekly prophylactic regimen with on-demand treatment and determined hemostatic efficacy in the treatment of bleeding episodes in 137 patients. These adolescents and adults were given either ADYNOVATE prophylaxis twice-weekly at a dose of 40–50 IU/kg (120 patients) or on-demand treatment with ADYNOVATE at a dose of 10–60 IU/kg (17 patients). The primary study goal was to compare ABR between the prophylaxis and on-demand treatment groups[2]
  - 95% reduction in median overall ABR (41.5 median ABR with on-demand [17 patients] vs 1.9 median ABR with prophylaxis [120 patients])
  - 0 bleeds in 40% (40 out of 101 per-protocol§ patients) during 6 months on twice-weekly prophylaxis

†Median is defined as the middle number in a list of numbers arranged in numerical order.
‡ABR=annualized bleed rate, the number of bleeds that occur over a year.
§Per-protocol patients were assigned to the prophylactic group and treated with their originally assigned dose for the entire duration of the study.

ADYNOVATE Important Information

What is ADYNOVATE?

- ADYNOVATE is an injectable medicine that is used to help treat and control bleeding in children and adults with hemophilia A (congenital factor VIII deficiency).
- Your healthcare provider (HCP) may give you ADYNOVATE when you have surgery.
- ADYNOVATE can reduce the number of bleeding episodes when used regularly (prophylaxis).

ADYNOVATE is not used to treat von Willebrand disease.

DETAILED IMPORTANT RISK INFORMATION

Who should not use ADYNOVATE?

Do not use ADYNOVATE if you:

- Are allergic to mouse or hamster protein.
- Are allergic to any ingredients in ADYNOVATE or ADVATE® [Antihemophilic Factor (Recombinant)].

Tell your HCP if you are pregnant or breastfeeding because ADYNOVATE may not be right for you.

What should I tell my HCP before using ADYNOVATE?

Tell your HCP if you:

- Have or have had any medical problems.
- Take any medicines, including prescription and non-prescription medicines, such as over-the-counter medicines, supplements or herbal remedies.
- Have any allergies, including allergies to mice or hamsters.
- Are breastfeeding. It is not known if ADYNOVATE passes into your milk and if it can harm your baby.
- Are or become pregnant. It is not known if ADYNOVATE may harm your unborn baby.
- Have been told that you have inhibitors to factor VIII (because ADYNOVATE may not work for you).

What important information do I need to know about ADYNOVATE?

- You can have an allergic reaction to ADYNOVATE. 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.
- Do not attempt to infuse yourself with ADYNOVATE unless you have been taught by your HCP or hemophilia center.

What else should I know about ADYNOVATE and Hemophilia A?

- Your body may form inhibitors to factor VIII. An inhibitor is part of the body's normal defense system. If you form inhibitors, it may stop ADYNOVATE from working properly. Talk with your HCP to make sure you are carefully monitored with blood tests for the development of inhibitors to factor VIII.

What are possible side effects of ADYNOVATE?

- The common side effects of ADYNOVATE are headache and nausea. These are not all the possible side effects with ADYNOVATE. Tell your HCP about any side effects that bother you or do not go away.

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 Important Facts about ADYNOVATE on the following page and discuss with your HCP.

For Full Prescribing Information, visit www.adynovate.com.

References: 1. Valentino LA. Considerations in individualizing prophylaxis in patients with haemophilia A. *Haemophilia*. 2014;20(5):607-615. **2**. ADYNOVATE Prescribing Information.

S49399 08/19

Takeda

ADYNOVATE
[Antihemophilic Factor (Recombinant), PEGylated]

Patient Important facts about

ADYNOVATE® [Antihemophilic Factor (Recombinant), PEGylated]

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

What is the most important information I need to know about ADYNOVATE?

Do not attempt to do an infusion to yourself unless you have been taught how by your healthcare provider or hemophilia center.

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

What is ADYNOVATE?

ADYNOVATE is an injectable medicine that is used to help treat and control bleeding in children and adults with hemophilia A (congenital Factor VIII deficiency). Your healthcare provider may give you ADYNOVATE when you have surgery. ADYNOVATE can reduce the number of bleeding episodes when used regularly (prophylaxis).

ADYNOVATE is not used to treat von Willebrand disease.

Who should not use ADYNOVATE?

You should not use ADYNOVATE if you:

- Are allergic to mice or hamster protein
- Are allergic to any ingredients in ADYNOVATE or ADVATE® [Antihemophilic Factor (Recombinant)]

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

How should I use ADYNOVATE?

ADYNOVATE is given directly into the bloodstream.

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

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

Reconstituted product (after mixing dry product with wet diluent) must be used within 3 hours and cannot be stored or refrigerated. Discard any ADYNOVATE left in the vial at the end of your infusion as directed by your healthcare professional.

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

How should I use ADYNOVATE? (cont'd)

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

What should I tell my healthcare provider before I use ADYNOVATE?

You should tell your healthcare provider if you:

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

What are the possible side effects of ADYNOVATE?

You can have an allergic reaction to ADYNOVATE.

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.

The common side effects of ADYNOVATE are headache and nausea. Tell your healthcare provider about any side effects that bother you or do not go away.

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

What else should I know about ADYNOVATE and Hemophilia A?

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

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

The risk information provided here is not comprehensive. To learn more, talk with your health care provider or pharmacist about ADYNOVATE. The FDA-approved product labeling can be found at www.ADYNOVATE.com or 1-877-825-3327.

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

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S47033

PAID CONSUMER OUTREACH

Matt Manzo

Information specialist

About Matt

Matt is a Hemophilia Community Liaison with almost 16 years of experience working within the hemophilia community. The commitment of patients and families to learning about this condition motivates him to be an information source for those living with hemophilia in the Midwestern area.

Hobbies

- Cross-country skiing
- Cycling

"It really is a privilege to get to know people living with hemophilia and everyone in the community."

Connect with Matt

ZZMQ@novonordisk.com
(248) 303-5848

Hemophilia Community Liaison

Novo Nordisk Inc., 800 Scudders Mill Road, Plainsboro, New Jersey 08536 U.S.A.

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Using Our Voices

Increasing Representation for Women with Bleeding Disorders

Shellye Horowitz

Shellye Horowitz

In November 2019 over 150 women gathered in Detroit for the 2nd Annual National Conference for Women with Hemophilia. The time spent together was as informative, empowering, and invigorating as the first conference held the year prior. The inaugural conference, held in 2018 was about being visible, acknowledging the presence of women with hemophilia in our community. The second conference focused on making our voices heard.

Throughout the conference, we learned strategies from top physicians on how women should seek access to treatment and care. **Dr. Meera Chitlur**, a phenomenal advocate for women with hemophilia and a member of the National Hemophilia Federation's (NHF) Medical and Scientific Advisory Council (MASAC), explained the critical work MASAC does to guide treatment protocols for individuals with bleeding disorders. We were, of course, most interested in the work they do to advocate for women. We learned that MASAC has a patient representative on their board (who currently happens to be male).

Through conversations between women at the second conference, we came up with a plan to petition MASAC to ensure there would always be a female patient representative. On the final morning of the conference, many women wrote letters to Dr. Chitlur, asking her to advocate on their behalf for the addition of a woman patient representative to MASAC. Dr. Chitlur not only received the letters and heard the community requests, but she also acted and advocated on our behalf.

I look forward to the day when our communities understand hemophilia is a disorder that affects us all, male and female, and women no longer need to "prove" that their hemophilia should be taken seriously.

~ Shellye Horowitz

We were THRILLED to learn this year, at the 3rd National Conference for Women and Teens with Hemophilia, that MASAC listened to and took this request to heart. Dr. Leonard Valentino, CEO of NHF, and Dr. Chitlur announced that MASAC will be including a woman patient representative and will work on identifying an individual to fill that role.

As a woman with hemophilia who is fortunate to be able to participate in the conferences, I cannot tell you how thrilled I was to learn that we, as a community, had impacted change. This is how we will continue to chart the course for women with bleeding disorders. Step by step we will initiate, educate, and help others to understand the struggles that women with hemophilia (and all bleeding disorders) face. It can often take years for medical practice to catch up with new scientific knowledge. We know that women can and do have hemophilia and struggle with bleeding issues. As we continue to advocate, we shorten the lag between knowledge and practice. All individuals with hemophilia deserve access to appropriate diagnosis, treatment, and care. I look forward to the day when our communities understand hemophilia is a disorder that affects us all, male and female, and women no longer need to "prove" that their hemophilia should be taken seriously.

Karen Boyd

Dave Rushlow

"Making a Difference One Person at a Time"

Special thanks to Karen Boyd, LMSW, and Dave Rushlow, LMSW, hemophilia treatment center social workers who facilitate the bimonthly Men's Support Group. We appreciate your dedication to your profession and the bleeding disorders community. Thank you!

Protecting Your Dental Health

Did you know that your dental health offers clues about your overall health — or that problems in your mouth can affect the rest of your body? Protect yourself by learning more about the connection between your dental health and overall health.

Visit our website for more information about ways to protect your dental health at: **www.hfmich.org/dental-health/.**

Need Dental Insurance?

If you are uninsured or underinsured with your dental coverage, we may be able to help. We understand that our community faces challenges obtaining dental care to meet unique and individual needs. HFM has partnered with Cascade Hemophilia Consortium to offer free dental insurance to those who need it.

*To maintain your coverage you must visit the dentist two times during the calendar year for regular teeth cleanings.

In order to be eligible for this program you must:

- Have a bleeding disorder
- Be a Michigan resident
- Have no dental insurance or only Children's Special Health Care Services
- However, if you have Medicare, Medicaid, or an employer based private insurance plan you may be eligible for limited-time coverage based on special circumstances – these exceptions are limited and determined on a case by case basis. Please call us for more information.

Questions? Contact **Lisa Clothier**, LMSW, ACSW, Outreach and Community Education Manager, at **lclothier@hfmich.org** or 734.961.3512.

You can find the application here: www.hfmich.org/dental-health/

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The Hemophilia Foundation of Michigan (HFM) exists to enhance the quality of life for all affected by bleeding disorders. HFM does not endorse any specific product or company. **www.hfmich.org**

staff

Pediatric Physicians: Dr. Steven Pipe; Dr. Elizabeth Quint; Dr. Jordan Shavit; Dr. Angela Weyand

Adult Physicians: Dr. Paula Bockenstedt; Dr. Suman Sood; Dr. Jordan Schaefer

Hemostasis/Thrombosis Fellows: Dr. Mary McGrath; Dr. Kristin Maher

Nursing Staff: Jim Munn, MS, BSN, RN-BC; Diana Mathis, BSN, RN-BC; Allan Kucab, BSN, RN

Physical Therapist: Sherry Herman-Hilker, PT, MS

Social Work: Laura McGinity, LMSW

Dental Hygienist: Karen Ridley, MSDH

Clinic Coordinator: Robin Pankey

Research Coordinators: Rebecca Hauke; Zachary Tigani, MPH

Center of Care University of Michigan Coagulation Disorders Program – HTC

Do you have any new staff members?

Dr. Jordan Schaefer, adult hematologist; Dr. Elizabeth Quint, pediatric and adolescent gynecology, Women's clinic; Dr. Mary McGrath, pediatric fellow; Dr. Kristin Maher, pediatric fellow; Allan Kucab, RN-BSN, nurse coordinator; Zachary Tigani MPH– research assistant and HHT coordinator

What is your catchment area?

All of Michigan, plus parts of northern Ohio and Indiana. We actually have patients who live across the country but come back here for care as they feel it is not the same in other parts of the US.

Do you serve pediatric or adult patients or are you a lifespan center?

Lifespan

When do your patients transition to an adult center?

When it is medically and/or psychosocially appropriate for the individual. As a lifespan center we have flexibility in transitions.

Where do those patients transfer?

To our adult physicians/clinic. All other staff cross-cover between pediatric and adult clinics.

How long has your HTC operated or when did it open?

In 1972, by Dr. John Penner.

Do you have any specialty clinics, outreach clinics, or programs that you would like to highlight?

- A combined clinic with gynecology and pediatric hematology with Dr. Quint and Dr. Weyand that serves girls and young women ages 12-25 with menstrual bleeding.
- Hereditary Hemorrhagic Telangiectasia program (HHT is a genetic disorder that affects about 1 in 5,000 to 1 in 10,000 people and is manifested by telangiectasias and arteriovenous malformations resulting in bleeding.) Dr. Sood is our physician lead for this program.
- Northville satellite clinic;
- Hemangioma and vascular anomalies specialty services;
- Anticoagulation management for pediatric patients followed in our clinic;
- Highly specialized coagulation lab;
- Interest in connective tissue disorders;
- A nationally recognized pediatric fellows training program specifically for physicians interested in coagulation disorders.

What do you see as your biggest strength as a center?

As a lifespan clinic we are able to continue seeing patients throughout their lives. We are also very involved in research studies and our team is internationally recognized. Our teamwork is unparalleled!

What inspires your staff?

Providing the best care possible for patients and families affected by hemostatic conditions – bleeding and clotting. We are inspired by seeing how lives can be changed by our collective efforts under the direction of the patient/parent.

Are you Sparty or Wolverine fans?

Duh! Maize and Blue runs through our veins, although our HHT Research Coordinator is a Sparty fan!

Contact:

University of Michigan Coagulation Disorders Program - HTC
1500 E. Medical Center Dr.,
Ann Arbor, MI, 48109-5235

P: 734.936.6393.

Michigan Women's Retreat

Shari Luckey

Like many other events in 2020, on Saturday, September 12th the annual Michigan Women's Retreat met in virtual land. While it was challenging not being in person, we were grateful to connect through a cozy Zoom experience. Perhaps the silver lining of meeting online was the delight of sending out 35 retreat boxes of supplies and goodies to the largest number of Women's Retreat attendees to date. A virtual event clearly provided access to some attendees that otherwise would not have been able to join us.

While everyone enjoyed lunch of their choice on us, we introduced ourselves and talked about bleeding disorders and the family. In between educational sessions and time to talk with industry sponsors, we were privileged to learn about honeybees from beekeeper Kathy Gerus-Darbison. It was a highly informative session, and we had the pleasure of each receiving a jar of honey from Kathy and her husband Bill's personal hive. Following the retreat one participant turned her jar of honey into beautiful loaves of honey bread.

We completed our time together with instruction from community member Brenda Martin on the art of book folding. Even with the challenge of teaching virtually, Brenda was able to get us all cutting and folding and on our way to a beautiful work of art.

Thank you to our sponsors, our staff, and most of all our attendees. It was truly a day of connection and renewal. **Save the Date for the 2021 Michigan Women's Retreat, May 15, 12-5p.**

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The Great Lakes Region Update

Sue Adkins

The Great Lakes Region Hemophilia Network proudly announces three hemophilia treatment center staff members that received awards at the American Thrombosis and Hemostasis Network (ATHN) Data Summit. **Rebecca Hauke** received the **Trish Dominic Award**. This award is given to an individual whose leadership has made a substantial impact on the direction of American Thrombosis and Hemostasis Network (ATHN). Following are comments made by ATHN leadership when virtually presenting the award to Becky. "For the past 23 years Becky has been at the University of Michigan Hemophilia and Coagulation Disorders Program in Ann Arbor, Michigan where she is the center's Research/Clinical Trial Coordinator and Database Administrator. Becky's contributions to the national data infrastructure predate ATHN's founding in 2006. She played an instrumental role in the design, launch, and continuous improvement of what is today called ATHN Systems. Her understanding of clinical data and the processes needed to acquire that data along with what motivates patient and family participation helped guide our development of ATHN Systems."

Heather Messenger, Dental Hygienist and Data Manager at the Michigan State University (MSU) Bleeding and Clotting Disorders Center, and **Lisa Littner**, Education Specialist at Cincinnati Children's Hospital Hemophilia Treatment Center, **were each awarded a CARE award this year.** The CARE award stands for Care through ATHN dataset Research and Evidence. Recipients will use the power of real-world data in the ATHN dataset to answer research questions and ultimately drive improvements in patient care. This competitive research opportunity is for members of the hemophilia treatment center interdisciplinary care team.

Heather's research project is entitled, "A Cross-Sectional Study of the American Thrombosis and Hemophilia Network Cohort for Hemophiliacs' and Dental Extraction Outcomes."

Lisa's research project is entitled, "Obesity and Inhibitors: The Prevalence and Strength of Association in People with Hemophilia."

We would also like to congratulate **Nancy Inverso**, Nurse Coordinator at West Michigan Cancer Center HTC, the new Great Lakes Region Representative to the National Hemophilia Foundation Nursing Work Group.

Thank you to those patients that participate in the CDC /ATHN Patient Registry. Your participation makes this research possible and drives improvement in bleeding disorder care.

Congratulations to each of these leaders.

HFM's Launch Program

Anthony Stevens

The Launch program supports employment preparedness for individuals living with bleeding disorders through resume building workshops, job training, certifications, interview skills workshops, and additional resources.

The goal of Launch is to assist post high school aged individuals within the bleeding disorders community that may be struggling to secure employment, meet the physical demands of current employment, or cannot financially support themselves through current employment. Launch provides the participants with several options within the vocational and certificate opportunities and offers assistance with entry into the program financially and instructionally as needed.

Through a partnership with MedCerts, a national certification company based out of Michigan, HFM is happy to announce that three participants have successfully completed certifications in the last year with certifications in phlebotomy, medical coding and billing, and pharmacy tech.

HFM Launch would not be possible without the support of our sponsor, Genentech. Thank you for your continued support of HFM's Launch program and our community.

Mental Health Care Matters!

As we head into these winter months, it is just as important to invest in our mental wellness as in our physical wellness. Having resources and tools to support your mental health can help you maintain your overall health. Visit our website at **www.hfmich.org/mental-health/** for helpful information and tools.

Social Distancing vs. Physical Distancing - Is it all semantics?

Lisa Clothier

Let's face it – 2020 has been a year like nothing we could have imagined as we were enjoying the holidays, ringing in the new year, and declaring our resolutions at the end of 2019.

We miss seeing our family, our friends, our co-workers. We miss running into old friends, and the freedom that was associated with a spontaneous get together – this separation can lead to feelings of isolation and affect our mental health. Social distancing is part of our reality – part of this "new normal" that we are all adjusting to. But, what if we could reframe "social distancing" and consider using the term "physical distancing" instead? It may seem like an insignificant change, but the words we use can affect how we feel.

The use of the term physical distancing in place of social distancing does NOT mean we are no longer maintaining a safe distance from others, rather that we do not have to isolate ourselves emotionally from others.

Can we find ways to connect while still maintaining the recommended minimum 6 feet of physical distance? I invite you to think about ways you might connect with someone in a new way. Think of some things that you can do virtually: play a game or host a movie night through Zoom, share old family photos via text and ask family and friends to share their memory of the photo, host Karaoke via Zoom, do a virtual cooking class with a friend – there are so many innovative ways to stay connected at no cost/low cost. You can also simply call to say "hi" and check in.

Especially with the holidays approaching, we may all be feeling the burden of emotional distancing. Let's step into the holiday season armored with ways to connect, reach out, and feel a part of something bigger. Wishing you peace, joy, and emotional connection.

Four Square Breathing Technique

Ever feel like you could use a stress reliever but don't have the time in your schedule to commit to something new? Try this quick and easy technique – you can do it anywhere and anytime!

Step 1: Gently exhale your breath
Step 2: Gently inhale through your nose while silently counting to 4
Step 3: Hold the breath for a count of 4
Step 4: Gently exhale the breath out of your mouth while silently counting to 4
Step 5: Hold the breath for a count of 4

Repeat these steps a couple of times as your body and mind begin to feel re-centered.

**This content is for educational purposes and is not intended to constitute medical advice.*



Community Nights

A special thank you to everyone that joined us for one of our virtual Community Nights in October and November. Together we learned new skills, had great fun, and most importantly had a chance to see one another. We cooked, we created, we mixed a zero-proof drink or three, we challenged our brains, and we were left with the belief that has always been held: That the HFM Community is wonderful!

SPECIAL THANKS TO HFM'S COMMUNITY NIGHT SPONSORS!

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Advocacy Summit

Every November, HFM hosts an Advocacy Summit to gather a variety of stakeholders familiar with legislative, health, and advocacy policy, who can lend their voice to local and national issues impacting the bleeding disorders community.

The 2020 Advocacy Summit was hosted virtually on November 23. While we missed the good food and opportunity to see each other in person, we are thankful for the ability to come together virtually.

Representatives from the National Hemophilia Foundation, the Hemophilia Federation of America, the Hemophilia Alliance, local hemophilia treatment centers, and industry governmental policy staff, joined HFM staff and community advocates. This diverse group of stakeholders allowed for an informative and encompassing discussion on health policy and access issues that may impact the bleeding disorders community.

We are thankful to all who participated!

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HFM's Advocacy Webinar Series

HFM hosted the first of our Advocacy Webinar series on May 19, 2020, called Shifting Perspectives. **We were joined by guest speakers, Jackie Prokop and Theresa Christner, from the Michigan Department of Health and Human Services** (MDHHS) to discuss policy changes within Medicaid and Children's Special Health Care Services due to the COVID-19 pandemic. We also shared the many ways community members could receive important information and connect with their local officials.

HFM's 2nd webinar focused on the growing insurance trend called copay accumulator programs. **Kollet Koulianos, Director of Payer Relations at the National Hemophilia Foundation**, has been leading the advocacy efforts around accumulator adjuster programs with employer groups. Kollet joined us to provide an overview of the issue to Michigan community members and answer questions.

We were also proud to host Michigan Representative Ben Frederick, sponsor of the copay accumulator reform legislation (HB 5944) in the MI House of Representatives. Rep. Frederick participated in the webinar and provided a few words on his legislation and the importance of protecting patients.

Our final and 3rd Advocacy Webinar will be held on December 16 and will focus on the copay accumulator legislation in Michigan, HB 5944. HFM will include updates on how patient organizations have been advocating and where the legislation currently stands.

Thank you to our speakers, sponsors, and attendees for participating in these important events.

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A Refreshing Walk Experience

Carrie McCulloch

If I had to describe the walks in one way this year, it would be: REFRESHING. Yes! Refreshing! Hosting virtual walks was far from our normal experience of strolling through the zoo, or this year taking a walk through the apple orchard; and certainly, it was disappointing not to see many of our familiar faces. Yet, the virtual walk gave us some opportunities that we might not have had in person.

We started each walk with a simple ice breaker question to match our Superhero theme: "If you had to create a super-persona, who would you be, and what would be your super-power?" Our walkers shared their answers through the chatbox. It felt like an insight into the creativity, thoughts, and HUMOR, that our community possesses. (A shout-out to "Potato Man": aka Ismael Jaber, whose super power is making fries disappear. And Bailey Hulswit who was "Super Cozy": spreading cozy feels everywhere.) What a fun thing it was to be able to see your ideas, as silly as the question may have been.

One of my favorite moments was having the chance to share my interview with our Board President, Jim Mohnach. At previous Detroit walks in person, you may have seen Jim hand out awards, and wave hello. During our virtual walk program, we were able to take a few minutes to introduce everyone to Jim and highlight the passion he brings to his service to the organization and the community as a whole. Thank you, Jim, for sharing your story as father to Aiden, an HFM superhero.

The superhero theme felt incredibly appropriate this year. As I shared with our walkers, superheroes don't come when things are easy. They come when things are hard, and they use their powers to make things better. Can you think of a better description of the walkers that supported HFM this year? Things ARE hard right now, but our walkers took a moment to think about their true motivations for walking and showed up without the promise of an activity like the zoo or apple orchard. They realized that the walk, much like camp, is not about the place. It is about the people, and the mission. We are so grateful to our walkers for standing by us.

A special thanks to Tim Wicks who served as my co-host… a co-host with many available costumes, and the super-power of humor on the fly. Anthony Stevens, Sarah Procario, Laura Olson, and Gwyn Hulswit were all helping on the back end to keep things running smoothly in this virtual world.

Mike Roth with Team Daphne and Tanner Godin with Team Tanner took home the top fundraising awards. These amazing teams were formed in honor of some of our youngest community members. What a wonderful way to show support. The Javorkas (of Team Daphne) even won some of our non-fundraising awards including best poster display!

My sincere hope is that life will allow us all to gather in person again next year. I would love to receive some hugs, to see some smiles, and to celebrate that we are together. But, if that can't happen, I am so glad to know that we can have an experience that is personal, FUN, and a celebration of the strong community that we are.

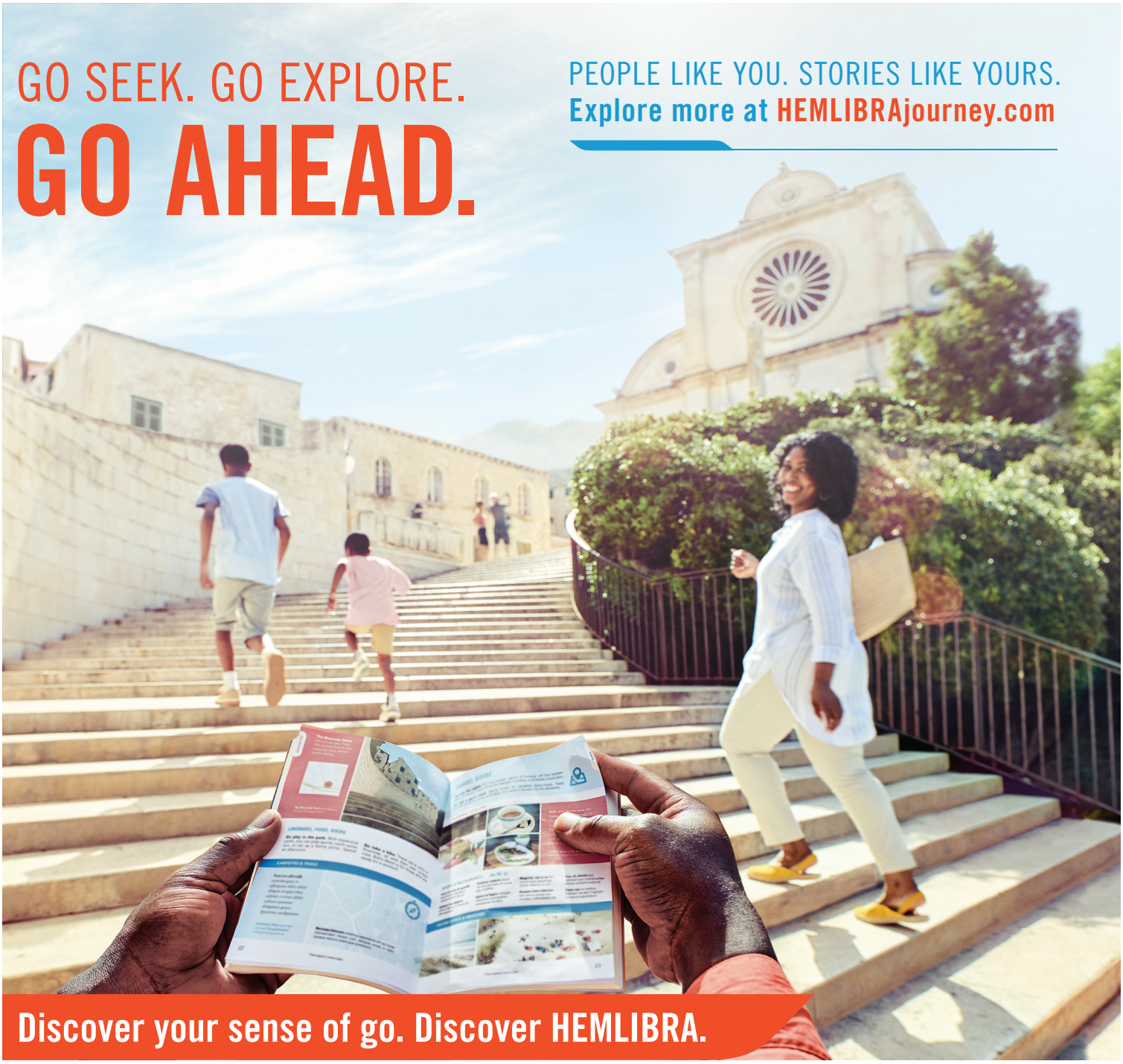
Thank you, superheroes.

GO SEEK. GO EXPLORE.

GO AHEAD.

PEOPLE LIKE YOU. STORIES LIKE YOURS.

Explore more at HEMLIBRAjourney.com



Discover your sense of go. Discover HEMLIBRA.

What is HEMLIBRA?

HEMLIBRA is a prescription medicine used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children, ages newborn and older, with hemophilia A with or without factor VIII inhibitors.

What is the most important information I should know about HEMLIBRA?

HEMLIBRA increases the potential for your blood to clot. People who use activated prothrombin complex concentrate (aPCC; Feiba®) to treat breakthrough bleeds while taking HEMLIBRA may be at risk of serious side effects related to blood clots.

These serious side effects include:

- **Thrombotic microangiopathy (TMA),** a condition involving blood clots and injury to small blood vessels that may cause harm to your kidneys, brain, and other organs
- **Blood clots (thrombotic events),** which may form in blood vessels in your arm, leg, lung, or head

Please see Brief Summary of Medication Guide on following page for Important Safety Information, including **Serious Side Effects**.

HEMLIBRA®
emicizumab-kxwh
injection for subcutaneous use
150 mg/mL

Medication Guide
HEMLIBRA® (hem-lee-bruh) (emicizumab-kxwh) injection, for subcutaneous use

What is the most important information I should know about HEMLIBRA?

HEMLIBRA increases the potential for your blood to clot. Carefully follow your healthcare provider's instructions regarding when to use an on-demand bypassing agent or factor VIII (FVIII) and the recommended dose and schedule to use for breakthrough bleed treatment.

HEMLIBRA may cause the following serious side effects when used with activated prothrombin complex concentrate (aPCC; FEIBA®), including:

- **Thrombotic microangiopathy (TMA).** This is a condition involving blood clots and injury to small blood vessels that may cause harm to your kidneys, brain, and other organs. Get medical help right away if you have any of the following signs or symptoms during or after treatment with HEMLIBRA:
  - confusion
  - weakness
  - swelling of arms and legs
  - yellowing of skin and eyes
  - stomach (abdomen) or back pain
  - nausea or vomiting
  - feeling sick
  - decreased urination
- **Blood clots (thrombotic events).** Blood clots may form in blood vessels in your arm, leg, lung, or head. Get medical help right away if you have any of these signs or symptoms of blood clots during or after treatment with HEMLIBRA:
  - swelling in arms or legs
  - pain or redness in your arms or legs
  - shortness of breath
  - chest pain or tightness
  - fast heart rate
  - cough up blood
  - feel faint
  - headache
  - numbness in your face
  - eye pain or swelling
  - trouble seeing

If aPCC (FEIBA®) is needed, talk to your healthcare provider in case you feel you need more than 100 U/kg of aPCC (FEIBA®) total.

See "**What are the possible side effects of HEMLIBRA?**" for more information about side effects.

What is HEMLIBRA?

HEMLIBRA is a prescription medicine used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children, ages newborn and older, with hemophilia A with or without factor VIII inhibitors.

Hemophilia A is a bleeding condition people can be born with where a missing or faulty blood clotting factor (factor VIII) prevents blood from clotting normally.

HEMLIBRA is a therapeutic antibody that bridges clotting factors to help your blood clot.

Before using HEMLIBRA, tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant. It is not known if HEMLIBRA may harm your unborn baby. Females who are able to become pregnant should use birth control (contraception) during treatment with HEMLIBRA.
- are breastfeeding or plan to breastfeed. It is not known if HEMLIBRA passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, or herbal supplements. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use HEMLIBRA?

See the detailed "Instructions for Use" that comes with your HEMLIBRA for information on how to prepare and inject a dose of HEMLIBRA, and how to properly throw away (dispose of) used needles and syringes.

- Use HEMLIBRA exactly as prescribed by your healthcare provider.
- **Stop (discontinue) prophylactic use of bypassing agents the day before starting HEMLIBRA prophylaxis.**
- **You may continue prophylactic use of FVIII for the first week of HEMLIBRA prophylaxis.**
- HEMLIBRA is given as an injection under your skin (subcutaneous injection) by you or a caregiver.
- Your healthcare provider should show you or your caregiver how to prepare, measure, and inject your dose of HEMLIBRA before you inject yourself for the first time.
- Do not attempt to inject yourself or another person unless you have been taught how to do so by a healthcare provider.
- Your healthcare provider will prescribe your dose based on your weight. If your weight changes, tell your healthcare provider.
- You will receive HEMLIBRA 1 time a week for the first four weeks. Then you will receive a maintenance dose as prescribed by your healthcare provider.
- If you miss a dose of HEMLIBRA on your scheduled day, you should give the dose as soon as you remember. You must give the missed dose as soon as possible before the next scheduled dose, and then continue with your normal dosing schedule. **Do not** give two doses on the same day to make up for a missed dose.
- HEMLIBRA may interfere with laboratory tests that measure how well your blood is clotting and may cause a false reading. Talk to your healthcare provider about how this may affect your care.

What are the possible side effects of HEMLIBRA?

- See "**What is the most important information I should know about HEMLIBRA?**"

The most common side effects of HEMLIBRA include:

- redness, tenderness, warmth, or itching at the site of injection
- headache
- joint pain

These are not all of the possible side effects of HEMLIBRA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store HEMLIBRA?

- Store HEMLIBRA in the refrigerator at 36°F to 46°F (2°C to 8°C). Do not freeze.
- Store HEMLIBRA in the original carton to protect the vials from light.
- Do not shake HEMLIBRA.
- If needed, unopened vials of HEMLIBRA can be stored out of the refrigerator and then returned to the refrigerator. HEMLIBRA should not be stored out of the refrigerator for more than a total of 7 days or at a temperature greater than 86°F (30°C).
- After HEMLIBRA is transferred from the vial to the syringe, HEMLIBRA should be used right away.
- Throw away (dispose of) any unused HEMLIBRA left in the vial.

Keep HEMLIBRA and all medicines out of the reach of children.

General information about the safe and effective use of HEMLIBRA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use HEMLIBRA for a condition for which it was not prescribed. Do not give HEMLIBRA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about HEMLIBRA that is written for health professionals.

What are the ingredients in HEMLIBRA?

Active ingredient: emicizumab-kxwh

Inactive ingredients: L-arginine, L-histidine, poloxamer 188, and L-aspartic acid.

Manufactured by: Genentech, Inc., A Member of the Roche Group,
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For more information, go to www.HEMLIBRA.com or call 1-866-HEMLIBRA.
This Medication Guide has been approved by the U.S. Food and Drug Administration
Revised: 10/2018

HEMLIBRA®
emicizumab-kxwh
injection for subcutaneous use
150 mg/mL

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Bleeder & a Buddy

In theme with the majority of HFM's 2020 programming, we welcomed 15 participants online for a virtual game night for our annual fall teen retreat, Bleeder and a Buddy. Teens and young adults joined together virtually to play games before competing in a bleeding disorders related escape room developed and facilitated by **Anne Henningfeld** from Beyond Recreation.

We are thankful for these opportunities to connect and appreciate the willingness of staff and participants to adapt to new events!

"As someone who has never been able to physically attend Old Beagle, CBE's Alumni Weekend, due to travel distance and work, getting the opportunity to connect virtually with my camp family was AMAZING!"

~ Anthony Pellecchia

FROM LEFT TO RIGHT: Tim Wicks, Andy Lawrence, Anthony Pellecchia, Antonio Jenkins, Allan Kucab, Travis Tussing, Phil Kucab. Circa 2000

Old Beagle

Anthony Pellecchia

Camp Bold Eagle (CBE) and Outpost have been a significant part of my life from 1999-2005. I was a counselor, program director, and head of The Early Eagle morning paper. Becoming part of the CBE family is without a doubt one of the most influential parts of my life. My desire to work in live theatre as a lighting designer and to teach design at the collegiate level unfortunately limited my ability to return to CBE and Outpost as an alum.

As someone who has never been able to physically attend Old Beagle, CBE's Alumni Weekend, due to travel distance and work, getting the opportunity to connect virtually with my camp family was AMAZING!

Reconnecting with so many incredible friends was such a highlight for me in these challenging times. Outside of one or two people, I rarely get the chance to visit with so many of my camp family at the same time. Virtual Old Beagle gave us the opportunity to reminisce about camp, as well as catch up and discuss our changing lives. Hearing about careers, seeing growing families and talking about what is new, had me feeling like I was back on the dock under the night stars.

I am grateful to everyone at HFM who diligently works on programming, education, and these types of events! As someone who hasn't been able to return to CBE or Outpost for 15 years, **you have brought camp back into this old beagle's life**.

Thank you to our sponsor Genentech A Member of the Roche Group

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Copays

ENSURING ALL COPAYS COUNT

Sarah Procario

What are Copay Accumulator Programs?

For individuals living with rare and chronic conditions, like hemophilia, cancer, and arthritis, the high cost of drugs has a direct impact on patient access. These patients often rely on copay assistance from manufacturers and nonprofit organizations, which save patients thousands of dollars in deductible and other out-of-pocket costs so that they can afford their lifesaving medication.

However, a new insurance trend is impacting copay assistance for patients. Under these policies, generally called "accumulator adjustment programs," copay assistance from manufacturers will no longer be applied toward patients' deductibles or out-of-pocket expenses.

Patients will still be able to use the copay card, but when the funds run out (typically a few months into the year) they will be responsible for their full deductible and maximum out-of-pocket costs. This shifts the burden on chronic and rare disease patients, who already face high out-of-pocket costs to maintain their rare or chronic conditions. As a result, these patients now may be required to pay thousands of dollars out-of-pocket for their medication all at once.

Pharmacy Benefit Managers (PBMs) and/or insurance companies argue accumulator adjuster programs incentivize patients to choose lower cost drug options. However, for many patients with rare and chronic disorders, lower cost alternatives are often not available. When implemented, the insurance plan and/or PBM accepts the full amount of the manufacturer copay card in addition to the deductible paid by the patient. The insurer ends up collecting more money while leaving patients struggling to access their prescription medication.

Copay Accumulator Reform

At the end of July 2020, a package of bills led by Health Policy Chairman Representative Hank Vaupel was introduced in the Michigan House of Representatives that aims to tackle drug pricing. Of these bills, one specifically affects patients who use manufacturer copay assistance–House Bill 5944.

As originally written, HB 5944 would disallow financial support from manufacturers to count towards a patient's deductible and total out of pocket (OOP) costs, following the increasingly utilized insurance practice called an "accumulator adjuster program."

Once we became aware of this bill package, HFM, the National Psoriasis Foundation, and the Arthritis Foundation organized a coalition including 14 other patient and provider organizations and began reaching out to members of the legislature to voice our concerns. Through close work with the bill sponsor, Representative Ben Frederick, and other legislative staff, we were able to agree on alternative language for HB 5944 that supports patients.

If passed, HB 5944 would ensure all copays paid on behalf of a patient count toward their deductible and out-of-pocket costs (unless there is a generic alternative that they have not already bypassed through their insurance protocols).

HFM continues to advocate for bleeding disorder patients to ensure you can access the medication you need without excessive cost-sharing requirements. If you would like to support our efforts, please visit **hfmich.org/advocacy** and join our action alert network.

Since this is an evolving issue, please see updates at **hfmich.org/news** as this situation may have changed since publication.

BOB has hemophilia A with inhibitors.

What is NovoSeven® RT?

NovoSeven® RT (coagulation Factor VIIa, recombinant) is an injectable medicine used for:

- Treatment of bleeding and prevention of bleeding for surgeries and procedures in adults and children with hemophilia A or B with inhibitors, congenital Factor VII (FVII) deficiency, and Glanzmann's thrombasthenia with a decreased or absent response to platelet transfusions
- Treatment of bleeding and prevention of bleeding for surgeries and procedures in adults with acquired hemophilia

Important Safety Information

What is the most important information I should know about NovoSeven® RT?

NovoSeven® RT may cause serious side effects, including:

- **Serious blood clots** that form in veins and arteries with the use of NovoSeven® RT have been reported
- Your healthcare provider should discuss the risks and explain the signs and symptoms of blood clots to you. Some signs of a blood clot may include pain, swelling, warmth, redness, or a lump in your legs or arms, chest pain, shortness of breath, or sudden severe headache and/or loss of consciousness or function
- Your healthcare provider should monitor you for blood clots during treatment with NovoSeven® RT
- You should not use NovoSeven® RT if you have ever had allergic (hypersensitivity) reactions, including severe, whole body reactions (anaphylaxis) to NovoSeven® RT, any of its ingredients, or mice, hamsters, or cows. Signs of allergic reaction include shortness of breath, rash, itching (pruritus), redness of the skin (erythema), or fainting/dizziness

novo nordisk®

Novo Nordisk Inc., 800 Scudders Mill Road, Plainsboro, New Jersey 08536 U.S.A.

In hemophilia with inhibitors,

Bleeds happen:

Take control with NovoSeven® RT

Controlling bleeds, whenever they happen

- Proven effective to treat hemophilia A or B with inhibitors, at home and in the hospital

Safety supported by clinical trial data

- Low rate (0.2%) of blood clots[a]

Speed when it's needed

- Fast to mix, fast to infuse, and fast to control bleeds[b]

NovoSeven® RT—committed to your experience

- More than 30 years of research and long-term clinical experience[c]

[a]For people with hemophilia A or B with inhibitors.
[b]Administer as a slow bolus injection over 2-5 minutes, depending on the dose administered.
[c]Compassionate use, also known as expanded access, began enrolling in 1988; FDA approval received in 1999.

Visit NovoSevenRT.com today to learn more

What should I tell my healthcare provider before using NovoSeven® RT?

- Tell your healthcare provider if you have any of the following, as these may increase your risk of blood clots:
  - congenital hemophilia and are also receiving treatment with aPCCs (activated prothrombin complex concentrates)
  - are an older patient particularly with acquired hemophilia and receiving other agents to stop bleeding
  - history of heart or blood vessel diseases
- Tell your healthcare provider and pharmacist about all the medicines you take, including all prescription and non-prescription medicines, such as over-the-counter medicines, supplements, or herbal remedies

What are the possible side effects of NovoSeven® RT?

- The most common and serious side effects are blood clots
- Tell your healthcare provider about any side effects that bother you or do not go away, and seek medical help right away if you have signs of a blood clot or allergic reaction

Please see Brief Summary of Prescribing Information on the following pages.

NovoSeven® RT
Coagulation Factor VIIa (Recombinant)

NOVOSEVEN® RT
Coagulation Factor VIIa (Recombinant)

Rx only

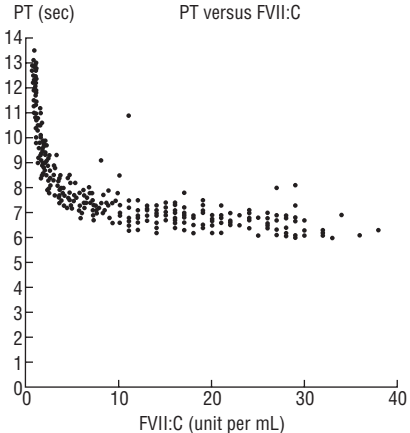
BRIEF SUMMARY. Please consult package insert for full prescribing information.

WARNING: THROMBOSIS: Serious arterial and venous thrombotic events following administration of NOVOSEVEN® RT have been reported. *[See Warnings and Precautions]* Discuss the risks and explain the signs and symptoms of thrombotic and thromboembolic events to patients who will receive NOVOSEVEN® RT. *[See Warnings and Precautions]* Monitor patients for signs or symptoms of activation of the coagulation system and for thrombosis. *[See Warnings and Precautions]*

INDICATIONS AND USAGE: NOVOSEVEN® RT, Coagulation Factor VIIa (Recombinant), is indicated for: Treatment of bleeding episodes and peri-operative management in adults and children with hemophilia A or B with inhibitors, congenital Factor VII (FVII) deficiency, and Glanzmann's thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets; Treatment of bleeding episodes and peri-operative management in adults with acquired hemophilia.

CONTRAINDICATIONS: None known.

WARNINGS AND PRECAUTIONS: Thrombosis: Serious arterial and venous thrombotic events have been reported in clinical trials and postmarketing surveillance. Patients with congenital hemophilia receiving concomitant treatment with aPCCs (activated prothrombin complex concentrates), older patients particularly with acquired hemophilia and receiving other hemostatic agents, or patients with a history of cardiac, vascular disease or predisposed to thrombotic events may have an increased risk of developing thrombotic events *[See Adverse Reactions and Drug Interactions]*. Monitor patients who receive NOVOSEVEN® RT for development of signs or symptoms of activation of the coagulation system or thrombosis. When there is laboratory confirmation of intravascular coagulation or presence of clinical thrombosis, reduce the dose of NOVOSEVEN® RT or stop the treatment, depending on the patient's condition. **Hypersensitivity Reactions:** Hypersensitivity reactions, including anaphylaxis, can occur with NOVOSEVEN® RT. Patients with a known hypersensitivity to mouse, hamster, or bovine proteins may be at a higher risk of hypersensitivity reactions. Discontinue infusion and administer appropriate treatment when hypersensitivity reactions occur. **Antibody Formation in Factor VII Deficient Patients:** Factor VII deficient patients should be monitored for prothrombin time (PT) and factor VII coagulant activity before and after administration of NOVOSEVEN® RT. If the factor VIIa activity fails to reach the expected level, or prothrombin time is not corrected, or bleeding is not controlled after treatment with the recommended doses, antibody formation may be suspected and analysis for antibodies should be performed. **Laboratory Tests:** Laboratory coagulation parameters (PT/INR, aPTT, FVII:C) have shown no direct correlation to achieving hemostasis. Assays of prothrombin time (PT/INR), activated partial thromboplastin time (aPTT), and plasma FVII clotting activity (FVII:C), may give different results with different reagents. Treatment with NOVOSEVEN® has been shown to produce the following characteristics: PT: As shown below, in patients with hemophilia A/B with inhibitors, the PT shortened to about a 7-second plateau at a FVII:C level of approximately 5 units per mL. For FVII:C levels > 5 units per mL, there is no further change in PT. The clinical relevance of prothrombin time shortening following NOVOSEVEN® RT administration is unknown.



INR: NOVOSEVEN® has demonstrated the ability to normalize INR. However, INR values have not been shown to directly predict bleeding outcomes, nor has it been possible to demonstrate the impact of NOVOSEVEN® on bleeding times/volume in models of clinically-induced bleeding in healthy volunteers who had received Warfarin, when laboratory parameters (PT/INR, aPTT, thromboelastogram) have normalized. aPTT: While administration of NOVOSEVEN® shortens the prolonged aPTT in hemophilia A/B patients with inhibitors, normalization has usually not been observed in doses shown to induce clinical improvement. Data indicate that clinical improvement was associated with a shortening of aPTT of 15 to 20 seconds. FVIIa:C: FVIIa:C levels were measured two hours after NOVOSEVEN® administration of 35 micrograms per kg body weight and 90 micrograms per kg body weight following two days of dosing at two hour intervals. Average steady state levels were 11 and 28 units per mL for the two dose levels, respectively.

ADVERSE REACTIONS: The most common and serious adverse reactions in clinical trials are thrombotic events. Thrombotic adverse reactions following the administration of NOVOSEVEN® in clinical trials occurred in 4% of patients with acquired hemophilia and 0.2% of bleeding episodes in patients with congenital hemophilia. **Clinical Trials Experience:** Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug product cannot be directly compared to rates in clinical trials of another drug, and may not reflect rates observed in practice. Adverse reactions outlined below have been reported from clinical trials and data collected in registries. Hemophilia A or B Patients with Inhibitors: In two studies for hemophilia A or B patients with inhibitors treated for bleeding episodes (N=298), adverse reactions were reported in ≥2% of the patients that were treated with NOVOSEVEN® for 1,939 bleeding episodes (see Table 3 below).

Table 3: Adverse Reactions Reported in ≥2% of the 298 Patients with Hemophilia A or B with Inhibitors

Body System Reactions	**# of adverse reactions** (n=1,939 treatments)	**# of patients** (n=298 patients)
Body as a whole		
Fever	16	13
Platelets, Bleeding, and Clotting		
Fibrinogen plasma decreased	10	5
Cardiovascular		
Hypertension	9	6

Serious adverse reactions included thrombosis, pain, thrombophlebitis deep, pulmonary embolism, decreased therapeutic response, cerebrovascular disorder, angina pectoris, DIC, anaphylactic shock and abnormal hepatic function. The serious adverse reactions of DIC and therapeutic response decreased had a fatal outcome. In two clinical trials evaluating safety and efficacy of NOVOSEVEN® administration in the perioperative setting in hemophilia A or B patients with inhibitors (N=51), the following serious adverse reactions were reported: acute post-operative hemarthrosis (n=1), internal jugular thrombosis adverse reaction (n=1), decreased therapeutic response (n=4). *Immunogenicity:* There have been no confirmed reports of inhibitory antibodies against NOVOSEVEN® or FVII in patients with congenital hemophilia A or B with alloantibodies. The incidence of antibody formation is 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 NOVOSEVEN® RT with the incidence of antibodies to other products may be misleading. Congenital Factor VII Deficiency: Data collected from the compassionate/emergency use programs, the published literature, a pharmacokinetics study, and the Hemophilia and Thrombosis Research Society (HTRS) registry showed that 75 patients with Factor VII deficiency had received NOVOSEVEN®: 70 patients for 124 bleeding episodes, surgeries, or prophylaxis; 5 patients in the pharmacokinetics trial. The following adverse reactions were reported: intracranial hypertension (n=1), IgG antibody against rFVIIa and FVII (n=1), localized phlebitis (n=1). *Immunogenicity:* In 75 patients with factor FVII deficiency treated with NOVOSEVEN® RT, one patient developed IgG antibody against rFVIIa and FVII. Patients with factor VII deficiency treated with NOVOSEVEN® RT should be monitored for factor VII antibodies. The incidence of antibody formation is 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 NOVOSEVEN® RT with the incidence of antibodies to other products may be misleading. Acquired Hemophilia: Data collected from four compassionate use programs, the HTRS registry, and the published literature showed that 139 patients with acquired hemophilia received NOVOSEVEN® for 204 bleeding episodes, surgeries and traumatic injuries. Of these 139 patients, 6 patients experienced 8 serious adverse reactions. Serious adverse reactions included shock (n=1), cerebrovascular accident (n=1) and thromboembolic events (n=6) which included cerebral artery occlusion, cerebral ischemia, angina pectoris, myocardial infarction, pulmonary embolism and deep vein thrombosis. Three of the serious adverse reactions had a fatal outcome. Glanzmann's Thrombasthenia: Data collected from the Glanzmann's Thrombasthenia Registry (GTR) and the HTRS registry showed that 140 patients with Glanzmann's thrombasthenia received NOVOSEVEN® RT for 518 bleeding episodes, surgeries or traumatic injuries. The following adverse reactions were reported: deep vein thrombosis (n=1), headache (n=2), fever (n=2), nausea (n=1), and dyspnea (n=1). **Post marketing Experience:** Adverse reactions reported during post marketing period were similar in nature to those observed during clinical trials and include reports of thromboembolic adverse events.

DRUG INTERACTIONS: Avoid simultaneous use of activated prothrombin complex concentrates. Do not mix NOVOSEVEN® RT with infusion solutions. Thrombosis may occur if NOVOSEVEN® RT is administered concomitantly with Coagulation Factor XIII. *[See Warnings and Precautions]*

USE IN SPECIFIC POPULATIONS: Pregnancy: Risk Summary: There are no adequate and well-controlled studies using NOVOSEVEN® RT in pregnant women to determine whether there is a drug-associated risk. Treatment of rats and rabbits with NOVOSEVEN® in reproduction studies has been associated with mortality at doses up to 6 mg per kg body weight and 5 mg per kg body weight respectively. At 6 mg per kg body weight in rats, the abortion rate was 0 out of 25 litters; in rabbits at 5 mg per kg body weight, the abortion rate was 2 out of 25 litters. Twenty-three out of 25 female rats given 6 mg per kg body weight of NOVOSEVEN® gave birth successfully, however, two of the 23 litters died during the early period of lactation. No evidence of teratogenicity was observed after dosing with NOVOSEVEN®. In the U.S. general population, the estimated background risk of major birth defect and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively. **Lactation:** Risk Summary: There is no information regarding the presence of NOVOSEVEN® RT in human milk, the effect on the breastfed infant, and the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for NOVOSEVEN® RT and any potential adverse effects on the breastfed infant from NOVOSEVEN® RT or from the underlying maternal condition. **Pediatric Use:** Clinical trials enrolling pediatric patients were conducted with dosing determined according to body weight and not according to age. Hemophilia A or B with Inhibitors: During the investigational phase of product development NOVOSEVEN® was used in 16 children aged 0 to <2 years for 151 bleeding episodes, 27 children aged 2 to <6 years for 140 bleeding episodes, 43 children aged 6 to <12 for 375 bleeding episodes and 30 children aged 12 to 16 years for 446 bleeding episodes. In a double-blind, randomized comparison trial of two dose levels of NOVOSEVEN® in the treatment of joint, muscle and mucocutaneous hemorrhages in hemophilia A and B patients with and without inhibitors 20 children aged 0 to <12 and 8 children aged 12 to 16 were treated with NOVOSEVEN® in doses of 35 or 70 micrograms per kg dose. Treatment was assessed as effective (definite relief of pain/tenderness as reported by the patient and/or a measurable decrease of the size of the hemorrhage and/or arrest of bleeding within 8 hours [rated as excellent = 51%], within 8-14 hours [rated as effective = 18%] or after 14 hours [rated as partially effective = 25%]) in 94% of the patients. NOVOSEVEN® was used in two trials in surgery. In a dose comparison 22 children aged 0 to 16 years were treated with NOVOSEVEN®. Effective intraoperative hemostasis (defined as bleeding that had stopped completely or had decreased substantially [rated as effective = 86%] or bleeding that was reduced but continued [rated as partially effective = 9%]) was achieved in 21/22 (95%) patients. Effective hemostasis was achieved in 10/10 (100%) patients in the 90 mcg/kg dose group and 10/12 (83%) in the 35 mcg/kg dose group at 48 hours; effective hemostasis was achieved in 10/10 (100%) in the 90 mcg/kg dose group and 9/12 (75%) in the 35 mcg/kg dose group at 5 days. In the surgery trial comparing bolus (BI) and continuous infusion (CI) 6 children aged 10 to 15 years participated, 3 in each group. Both regimens were 100% effective (defined as bleeding has stopped completely, or decreased substantially) intra-operatively, through the first 24 hours and at day 5. At the end of the study period (Postoperative day 10 or discontinuation of therapy) hemostasis in two patients in the BI group was rated effective and hemostasis in one patient was rated as ineffective (defined as bleeding is the same or has worsened). Hemostasis in all three patients in the CI group was rated as effective. Adverse drug reactions in pediatric patients were similar to those previously reported in clinical trials with NOVOSEVEN®, including one thrombotic event in a 4 year old with internal jugular vein thrombosis after port-a-cath placement which resolved. Congenital Factor VII deficiency: In published literature, compassionate use trials and registries on use of NOVOSEVEN® in congenital Factor VII deficiency, NOVOSEVEN® was used in 24 children aged 0 to <12 years and 7 children aged 12 to 16 years for 38 bleeding episodes, 16 surgeries and 8 prophylaxis regimens. Treatment was effective in 95% of bleeding episodes (5% not rated) and 100% of surgeries. No thrombotic events were reported. A seven-month old exposed to NOVOSEVEN® and various plasma products developed antibodies against FVII and rFVIIa [*see Adverse Reactions and Overdosage*]. Glanzmann's Thrombasthenia: In the Glanzmann's Thrombasthenia Registry, NOVOSEVEN® was used in 43 children aged 0 to 12 years for 157 bleeding episodes and in 15 children aged 0 to 12 years for 19 surgical procedures. NOVOSEVEN® was also used in 8 children aged >12 to 16 years for 17 bleeding episodes and in 3 children aged >12 to 16 years for 3 surgical procedures. Efficacy of regimens including NOVOSEVEN® was evaluated by independent adjudicators as 93.6% and 100% for bleeding episodes in children aged 0 to 12 years and >12 to 16 years, respectively. Efficacy in surgical procedures was evaluated as 100% for all surgical procedures in children aged 0 to 16 years. No adverse reactions were reported in Glanzmann's thrombasthenia children. **Geriatric Use:** Clinical studies of NOVOSEVEN® RT in congenital factor deficiencies and Glanzmann's thrombasthenia did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

OVERDOSAGE: Dose limiting toxicities of NOVOSEVEN® RT have not been investigated in clinical trials. The following are examples of accidental overdose. One newborn female with congenital factor VII deficiency was administered an overdose of NOVOSEVEN® (single dose: 800 micrograms per kg body weight). Following additional administration of NOVOSEVEN® and various plasma products, antibodies against rFVIIa were detected, but no thrombotic complications were reported. One Factor VII deficient male (83 years of age, 111.1 kg) received two doses of 324 micrograms per kg body weight (10-20 times the recommended dose) and experienced a thrombotic event (occipital stroke). One hemophilia B patient (16 years of age, 68 kg) received a single dose of 352 micrograms per kg body weight and one hemophilia A patient (2 years of age, 14.6 kg) received doses ranging from 246 micrograms per kg body weight to 986 micrograms per kg body weight on five consecutive days. There were no reported complications in either case.

More detailed information is available upon request.

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2880 Bagsvaerd, Denmark
License Number: 1261

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NovoSeven® RT
Coagulation Factor VIIa (Recombinant)

2021

Due to the continued COVID-19 pandemic, and based on consultation with many physicians in the bleeding disorders community, as well as the recommendation of the National Hemophilia Foundation, all of **HFM's events and programs will continue to be virtual through June 2021**.

We miss seeing you all but we are grateful that we have the technology to connect, learn, and be together.

Please look for our **2021 events postcard in February**. We're looking forward to engaging with and seeing all of you, whether online or in person.

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Ypsilanti, Michigan 48197

Connecting

"The Annual Women's Retreat is a no-miss event, centered on women, education, and most of all, fun! The programming is outstanding and I learn something new each time I am able to attend. The opportunity to catch up with friends and make new memories is more than an added bonus."

~ Suzan Higgins

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