

# FACTOR NOTES

BROUGHT TO YOU BY THE SOUTHWESTERN OHIO HEMOPHILIA FOUNDATION



Since our last newsletter, much has changed and yet much has remained the same. SWOHF may not physically be in the office, but we are still working--still here to help. Even as we practice social distancing, we can remain connected through kindness and generosity, creativity and encouragement.

SWOHF Board and staff are committed to keeping the safety/health of our members and sponsors in mind as decisions are made about future events. We believe that together we will come out stronger on the other side of all this as we find ways to see the good in others and be the good in our Greater Dayton area. As a community, we can still provide financial, emotional and social supports that nurture our families.

Because our sponsors have been such a vital part of the past success of our fundraisers, we have made a list below of companies that have sponsored our Golf Outing -- some for many years. These are small businesses who could really use our support right now. Even though our Golf Outing has been postponed to 2021, we can still show appreciation for those whose generosity has impacted us in past years.

## 2020 ISSUE #2



### TEE SPONSORS

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### GOLF COURSES

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Soft Touch Car Wash  
Sweeney's Seafood  
The Old Bag of Nails  
The Spicy Olive  
Wagner Subaru

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### SOUTHWESTERN OHIO HEMOPHILIA FOUNDATION

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info@swohf.org

# WATCH FOR UPDATES

Some 2020 SWOHF events could go virtual; others may be postponed or adjusted. Decisions will be made on these upcoming events as more information is available. Check the website [swohf.org](http://swohf.org) for the most current info.

**SEPTEMBER 19 - 5K**

**OCTOBER 11 - FALL OUTING**

**NOVEMBER 14 - WOMEN'S DAY TOGETHER**

**DECEMBER 5 - TEEN EVENT**

**TBD - BOMBARDIER BLOOD MOVIE**

## DO YOU WANT TO RECEIVE FUTURE CALENDAR UPDATES?

Then, we need your email! Now it's more important than ever that SWOHF has your correct email and home address. SWOHF emails are sent through Network For Good, our database management program. If you're not getting emails, first check your spam/junk folder since they are sent as group blasts. If there's nothing there, please contact us so we can update our records with your current information. Call 937-298-8000 and leave a message OR email [office@swohf.org](mailto:office@swohf.org). If members of your household have different emails, SWOHF would like to be able to send directly to all individuals. Especially for teens, we need individual emails to notify of upcoming "teen only" events.



SUMMER  
EVENTS  
MOVED TO  
**2021**

### SWOHF 2020 SUMMER CALENDAR UPDATE

Summer Events cancelled for 2020:  
**Family Fest & Golf Outing**



Moved from 2020 to June 25-27, 2021



Moved from 2020 to August 19, 2021



**SWOHF**  
SOUTHWESTERN OHIO  
HEMOPHILIA FOUNDATION



HFM Bold Eagle Camps will likely move to a virtual platform. Contact HTC for more info.

Check website for updates [www.swohf.org](http://www.swohf.org)

Contact us: 937-298-8000  
Email Kay: [kay@swohf.org](mailto:kay@swohf.org)

## GOING VIRTUAL!

A FULLY VIRTUAL  
CONFERENCE  
August 1-8, 2020



Every year NHF's Bleeding Disorders Conference brings together thousands of families for education and networking. This year, in order to keep our community safe and help prevent the spread of COVID-19 NHF has made the decision to host the 2020 Bleeding Disorders Conference virtually. One of our greatest strengths is our ability to adapt and reinvent ourselves when needed. Check the NHF website [hemophilia.org](http://hemophilia.org) for more info.

We are excited to share that the 2020 HFA Annual Symposium will take place virtually on Monday, Aug. 24, through Saturday, Aug. 29. Registration for attendees will be free. HFA will be working hard in the coming weeks to create an event you will love!

If you have any questions, please visit their website [hemophiliafed.org](http://hemophiliafed.org) or email [symposium@hemophiliafed.org](mailto:symposium@hemophiliafed.org).

**SYMPOSIUM  
IS GOING  
VIRTUAL!**

August 24-29, 2020

Learn more about this exciting event here!



# VOLUNTEER OF THE YEAR: DEBRA KREMER-SMITH



Deb has served SWOHF selflessly for many years. She has held the office of Secretary on the Board, served as Chair of Family Fest and volunteered at the Golf Outing and Fall Outing year after year. She has two sons, two brothers and a grand-nephew with hemophilia. Her mother played a key role in building our Foundation. She was Board Secretary for many years and so it only seemed natural that Deb would follow in her footsteps. Deb has often said, "In a world where you can be anything, be kind!" She also has a heart for making others feel a great sense of belonging! Her generosity with her time and talents has contributed to SWOHF being what it is today. We applaud and appreciate her dedication and commitment through the years!



*All SWOHF Volunteers attending were recognized at our Annual Meeting.*

# TEENS TOP GOLF!



On Saturday, February 15, SWOHF teens and staff gathered for a brief meeting and trip to Top Golf in Cincinnati. The teens enjoyed indoor golf, giveaways, great food--even injectable donut holes! (see pic below). Special Thanks to HFA for sponsoring this event and providing our speaker, Michelle Cecil, who discussed college considerations for those with bleeding disorders.



GO SEEK. GO EXPLORE.  
**GO AHEAD.**

PEOPLE LIKE YOU. STORIES LIKE YOURS.  
Explore more at [HEMLIBRAjourney.com](https://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. Carefully follow your healthcare provider's instructions regarding when to use an on-demand bypassing agent or factor VIII, and the dose and schedule to use for breakthrough bleed treatment. HEMLIBRA may cause serious side effects when used with activated prothrombin complex concentrate (aPCC; FEIBA®), including thrombotic microangiopathy (TMA), and blood clots (thrombotic events). 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.**

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



**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
  - 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,  
1 DNA Way, South San Francisco, CA 94080-4990  
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For more information, go to [www.HEMLIBRA.com](http://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



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A Member of the Roche Group

# ANNUAL MEETING

SWOHF Annual Meeting was held on Saturday, March 7 at the Beaver Creek Golf Club. Over 70 individuals attended and our morning together included:

- Buffet breakfast with made-to-order omelets
- Industry partner displays
- Financial and Program Reports from Board
- Advocacy Initiatives Summary from Ohio Bleeding Disorders Council Parent Ambassador
- 25th Anniversary Video History of FamOhio and Speakers: Teresa and Dwanna Rutter
- Presentation of \$5,000 Grant from FamOhio to SWOHF Board
- Update from our Dayton Children's HTC by Melissa Tucker, RN CPN
- Showing our appreciation for all our 2019 Volunteers with the gift of a SWOHF HydroFlask
- Honoring our VOLUNTEER of the Year: DEB KREMER-SMITH

A copy of the program/handout, including 2019 financial reports and event summaries, is available from the SWOHF Office upon request. The FamOhio video is available on YouTube [www.youtube.com/watch?v=K9KqcqUXHrE](http://www.youtube.com/watch?v=K9KqcqUXHrE)



SPONSORS FOR OUR  
2020 ANNUAL MEETING



# WASHINGTON DAYS 2020

SWOHF advocates included: Daniel and Louis Weaver, Brittany Jackson (HTC-Social Worker), Beth Linegang (HTC), Melissa Tucker (HTC) and Kay Clark (Exec Director). We met with Legislative Assistants in the offices of Sen. Rob Portman, Sen. Sherrod Brown, Rep. Warren Davidson, and Rep. Michael Turner.

More than 400 members of the bleeding disorders community put on their red ties in Washington DC to meet with their Members of Congress and share how federal legislation and funding affects people with bleeding disorders. The annual event, which was held February 26-28, provides advocates with talking points, training, and leave-behind materials.

This year's focus was the Hemophilia Skilled Nursing Facilities Access Act, legislation that would allow skilled nursing facilities (SNFs) to bill Medicare for clotting factor separately. Currently, SNF's cannot do this, which results in people with bleeding disorders who receive Medicare being denied access to these facilities after surgery or serious bleeding episode. Volunteer advocates asked their legislators to co-sponsor the bipartisan bills. The second request made by advocates was to maintain funding for hemophilia programs at federally funded hemophilia treatment centers and research that pertains to bleeding disorders.

Attendees also received training on how to advocate with their state and local governments. Special Guest Speaker




was Ohio's very own **Randi Clites**, State Representative of the 75th District of Ohio, who had recently announced the unanimous vote of the Ohio House Health Committee to favorably report House Bill 412, to create the Ohio Rare Disease Advisory Council. Rep. Clites and Rep. Tim Ginter (R-Salem) are joint sponsors of the bill. The bill would bring together medical researchers, physicians, nurses, patients, lawmakers and state officials to begin addressing many of the issues facing those living with rare diseases.

*"This council would provide the expertise that lawmakers need to solve the issues facing those living with a rare disease, pave the way for better healthcare policy in the state, and deliver better access to government to those living with a rare disease," said Rep. Clites. The full article "Hemophilia Mom Turned Ohio Legislator Proposes Rare Disease Advisory Council" is available in the Winter 2019 Issue of "Factor Nine News" published by The Coalition for Hemophilia B and can be found on their website [www.hemob.org](http://www.hemob.org)*



## THE EXTENDED-HALF-LIFE rFVIII WITH PROVEN PROTECTION AND UNIQUE STEP-WISE DOSING<sup>1,2</sup>

For patients  $\geq 12$  years

|              |  |  |
|--------------|--|--|
| Start simply | <b>TWICE WEEKLY</b>  | <b>For all prophylaxis patients:</b><br>Recommended starting regimen is Jivi twice weekly (30-40 IU/kg) <sup>1</sup>   |
| Step up      | <b>EVERY 5 DAYS</b>  | <b>Based on bleeding episodes:</b><br>Less frequent dosing of Jivi every 5 days (45-60 IU/kg) can be used <sup>1</sup> |
| Fine tune    |  | <b>Based on bleeding episodes:</b><br>The dosing frequency may be further adjusted up or down <sup>1</sup>             |

IU, international units; kg, kilograms; rFVIII, recombinant Factor VIII.

### INDICATIONS

- Jivi is an injectable medicine used to replace clotting factor (Factor VIII or antihemophilic factor) that is missing in people with hemophilia A.
- Jivi is used to treat and control bleeding in previously treated adults and adolescents (12 years of age and older) with hemophilia A. Your healthcare provider may also give you Jivi when you have surgery. Jivi can reduce the number of bleeding episodes in adults and adolescents with hemophilia A when used regularly (prophylaxis).
- Jivi is not for use in children below 12 years of age or in previously untreated patients.
- Jivi is not used to treat von Willebrand disease.

### IMPORTANT SAFETY INFORMATION

- You should not use Jivi if you are allergic to rodents (like mice and hamsters) or to any ingredients in Jivi.
- Tell your healthcare provider about all of your medical conditions that you have or had.
- Tell your healthcare provider if you have been told that you have inhibitors to Factor VIII.
- Allergic reactions may occur with Jivi. Call your healthcare provider right away and stop treatment if you get tightness of the chest or throat, dizziness, decrease in blood pressure, or nausea.
- Allergic reactions to polyethylene glycol (PEG), a component of Jivi, are possible.
- Your body can also make antibodies, called “inhibitors,” against Jivi, which may stop Jivi from working properly. Consult your healthcare provider to make sure you are carefully monitored with blood tests for the development of inhibitors to Factor VIII.





**FEEL EMPOWERED**  
to step up to the challenge  
with **Jivi<sup>®</sup>**

Ask your doctor if Jivi<sup>®</sup> may be right for you. Learn more at [www.jivi.com](http://www.jivi.com).

### IMPORTANT SAFETY INFORMATION (CONT'D)

- If your bleeding is not being controlled with your usual dose of Jivi, consult your doctor immediately. You may have developed Factor VIII inhibitors or antibodies to PEG and your doctor may carry out tests to confirm this.
- The common side effects of Jivi are headache, cough, nausea, and fever.
- These are not all the possible side effects with Jivi. Tell your healthcare provider about any side effect that bothers you or that does not go away.

For additional important risk and use information, please see the Brief Summary on the following page.

You are encouraged to report side effects or quality complaints of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

**References:** 1. Jivi<sup>®</sup> Prescribing Information. Whippany, NJ: Bayer LLC; 2018.  
2. Data on file. Tx Review 0918. Bayer; 2018.

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antihemophilic factor  
(recombinant) PEGylated-auct  
**LET'S GO**

# HIGHLIGHTS OF FDA-Approved Patient Labeling

## Patient Information

### Jivi (*JHIV-ee*) antihemophilic factor (recombinant), PEGylated-aucl

This leaflet summarizes important information about Jivi with vial adapter. 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 Jivi. If you have any questions after reading this, ask your healthcare provider.

**Do not attempt to self-infuse, unless your healthcare provider or hemophilia center has taught you how to self-infuse.**

#### What is Jivi?

Jivi is an injectable medicine used to replace clotting factor (Factor VIII or antihemophilic factor) that is missing in people with hemophilia A (congenital Factor VIII deficiency).

Jivi is used to treat and control bleeding in previously treated adults and adolescents (12 years of age and older) with hemophilia A. Your healthcare provider may also give you Jivi when you have surgery. Jivi can reduce the number of bleeding episodes in adults and adolescents with hemophilia A when used regularly (prophylaxis).

Jivi is not for use in children < 12 years of age or in previously untreated patients.

Jivi is not used to treat von Willebrand disease.

#### Who should not use Jivi?

You should not use Jivi if you

- are allergic to rodents (like mice and hamsters).
- are allergic to any ingredients in Jivi.

#### What should I tell my healthcare provider before I use Jivi?

Tell your healthcare provider about:

- All of your medical conditions that you have or had.
- All of the medicines you take, including all prescription and non-prescription medicines, such as over-the-counter medicines, supplements, or herbal remedies.
- Pregnancy or planning to become pregnant. It is not known if Jivi may harm your unborn baby.
- Breastfeeding. It is not known if Jivi passes into the milk.
- Whether you have been told that you have inhibitors to Factor VIII.

#### What are the possible side effects of Jivi?

The common side effects of Jivi are headache, cough, nausea and fever.

Allergic reactions may occur with Jivi. Call your healthcare provider right away and stop treatment if you get tightness of the chest or throat, dizziness, decrease in blood pressure, or nausea. Allergic reactions to polyethylene glycol (PEG), a component of Jivi, are possible.

Your body can also make antibodies, called “inhibitors”, against Jivi, which may stop Jivi 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.

If your bleeding is not being controlled with your usual dose of Jivi, consult your doctor immediately. You may have developed Factor VIII inhibitors or antibodies to PEG and your doctor may carry out tests to confirm this.

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

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

#### How do I store Jivi?

Do not freeze Jivi.

Store Jivi at +2°C to +8°C (36°F to 46°F) for up to 24 months from the date of manufacture. Within this period, Jivi may be stored for a period of up to 6 months at temperatures up to +25°C or 77°F.

Record the starting date of room temperature storage clearly on the unopened product carton. Once stored at room temperature, do not return the product to the refrigerator. The product then expires after storage at room temperature for 6 months, or after the expiration date on the product vial, whichever is earlier. Store vials in their original carton and protect them from extreme exposure to light.

Administer reconstituted Jivi as soon as possible. If not, store at room temperature for no longer than 3 hours.

Throw away any unused Jivi after the expiration date.

Do not use reconstituted Jivi if it is not clear.

#### What else should I know about Jivi and hemophilia A?

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

This leaflet summarizes the most important information about Jivi that was written for healthcare professionals.

#### Resources at Bayer available to the patient:

For Adverse Reaction Reporting, contact Bayer Medical Communications 1-888-84-BAYER (1-888-842-2937)

To receive more product information, contact Jivi Customer Service 1-888-606-3780

Bayer Reimbursement HELPLine 1-800-288-8374

For more information, visit <http://www.Jivi.com>

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# EXCITING NHF & HFA NEWS

## NHF WELCOMES NEW CEO

SWOHF welcomes NHF's new Chief Executive Officer, Dr. Leonard Valentino. For over three decades he has treated families with bleeding disorders, working towards finding better treatments for patients and preventing complications of their disorders through education, advocacy, and research.

He earned his undergraduate and medical degree from Creighton University and Creighton University School of Medicine. Then he went on to attend the University of Illinois at Chicago's Pediatric Medicine Residency prior to a fellowship in pediatric hematology-oncology at the David Geffen School of Medicine at UCLA.

Dr. Valentino wrote, "NHF's dedication to education, advocacy, and research in discovering innovative, essential treatments and cures is unmatched. That, along with the foundation's deep-rooted history and the individual strength of each chapter, sets NHF apart." In this new phase of NHF leadership, Dr. Valentino is committed to working collaboratively and directly with Chapter leadership. SWOHF looks forward to working with NHF in our joint pursuit to improve the outcomes for OUR community.



**NATIONAL HEMOPHILIA FOUNDATION**  
*for all bleeding disorders*



## HFA WELCOMES NEW CEO

Hemophilia Federation of America announced the board of directors has selected Sharon Meyers, M.S., CFRE, as president and chief executive officer, effective Jan. 16, 2020.

Meyers has 15 years of healthcare and university nonprofit leadership experience at the local, state, regional and national level.

Meyers is a Certified Fund Raising Executive (CFRE) and holds a Nonprofit Management Executive Certificate from Georgetown University. She is currently working on a doctorate in education at the University of Southern California in Organizational Change and Leadership. Additionally, she holds a master's in political science from the University of Southern Mississippi.



## WORKING TOGETHER



REACH GOALS



SUPPORT



TEAM SPIRIT



COLLABORATION



COMMUNICATION



EXCHANGE

When it comes to your hemophilia A treatment

# Move beyond the threshold<sup>a</sup>

Esperoct<sup>®</sup> can give you high factor levels for longer.<sup>b</sup>

Extend half-life beyond the standard 22-hour average half-life in adults<sup>c</sup>

## FOR ADULTS AND ADOLESCENTS

### Switching made easy with a standard 50 IU/kg dose every 4 days

-50% fewer infusions if you previously infused every other day

-40% fewer infusions if you previously infused 3x a week

### High factor levels

At or above 3%  
for 100% of the time<sup>d,e</sup>

At or above 5%  
for 90% of the time<sup>d,f</sup>

### Flexible on the go

The ONLY extended half-life product that can be stored up to 104°F<sup>g</sup>

Please see Brief Summary for complete storage instructions.

## Safety Proven across 5 studies, the largest and longest EHL clinical trial program

<sup>a</sup>Of 1% trough factor levels for standard half-life (SHL) products in adults and adolescents.

<sup>b</sup>Compared with SHL products.

<sup>c</sup>Data shown are from 42 adults who received a pharmacokinetic (PK) assessment around the first Esperoct<sup>®</sup> 50 IU/kg dose.

<sup>d</sup>Trough level goal is 1% for prophylaxis.

<sup>e</sup>Data shown are from a study where 175 previously treated adolescents and adults received routine prophylaxis with Esperoct<sup>®</sup> 50 IU/kg every 4 days.

<sup>f</sup>Pre-dose factor activity (trough) levels were evaluated at follow-up visits. Mean trough levels for adolescents (12-<18 years) were 2.7 IU/dL.

<sup>g</sup>Steady-state FVIII activity levels were estimated in 143 adults and adolescents using pharmacokinetic modeling.

<sup>h</sup>For up to 3 months.

### What is Esperoct<sup>®</sup>?

Esperoct<sup>®</sup> [antihemophilic factor (recombinant), glycopegylated-exe] is an injectable medicine to treat and prevent or reduce the number of bleeding episodes in people with hemophilia A. Your healthcare provider may give you Esperoct<sup>®</sup> when you have surgery

- Esperoct<sup>®</sup> is not used to treat von Willebrand Disease

### IMPORTANT SAFETY INFORMATION

#### Who should not use Esperoct<sup>®</sup>?

- You should not use Esperoct<sup>®</sup> if you are allergic to factor VIII or any of the other ingredients of Esperoct<sup>®</sup> or if you are allergic to hamster proteins

#### What is the most important information I need to know about Esperoct<sup>®</sup>?

- Do not attempt to do an infusion yourself unless you have been taught how by your healthcare provider or hemophilia treatment center
- Call your healthcare provider right away or get emergency treatment right away if you get any signs of an allergic reaction, such as: hives, chest tightness, wheezing, dizziness, difficulty breathing, and/or swelling of the face

### What should I tell my healthcare provider before using Esperoct<sup>®</sup>?

- Before taking Esperoct<sup>®</sup>, you should tell your healthcare provider if you have or have had any medical conditions, take any medicines (including non-prescription medicines and dietary supplements), are nursing, pregnant or planning to become pregnant, or have been told that you have inhibitors to factor VIII

- Your body can make antibodies called "inhibitors" against Esperoct<sup>®</sup>, which may stop Esperoct<sup>®</sup> from working properly.

#### Call your healthcare provider right away if your bleeding does not stop after taking Esperoct<sup>®</sup>

### What are the possible side effects of Esperoct<sup>®</sup>?

- Common side effects of Esperoct<sup>®</sup> include rash or itching, and swelling, pain, rash or redness at the location of infusion

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

Discover more at [Esperoct.com](https://www.esperoct.com).



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

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**esperoct<sup>®</sup>**

*antihemophilic factor (recombinant), glycopegylated-exe*

# esperoct®

*antihemophilic factor (recombinant), glycopegylated-exei*

## **Brief Summary information about ESPEROCT® [antihemophilic Factor (recombinant), glycopegylated-exei]**

This information is not comprehensive.

- Talk to your healthcare provider or pharmacist
- Visit [www.novo-pi.com/esperoct.pdf](http://www.novo-pi.com/esperoct.pdf) to obtain FDA-approved product labeling
- Call 1-800-727-6500

## **Patient Information**

### **ESPEROCT® [antihemophilic factor (recombinant), glycopegylated-exei]**

**Read the Patient Information and the Instructions For Use that come with ESPEROCT® before you start taking this medicine and each time you get a refill. There may be new information.**

This Patient Information does not take the place of talking with your healthcare provider about your medical condition or treatment. If you have questions about ESPEROCT® after reading this information, ask your healthcare provider.

### **What is the most important information I need to know about ESPEROCT®?**

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

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

### **What is ESPEROCT®?**

ESPEROCT® is an injectable medicine used to replace clotting Factor VIII that is missing in patients with hemophilia A. Hemophilia A is an inherited bleeding disorder in all age groups that prevents blood from clotting normally.

ESPEROCT® is used to treat and prevent or reduce the number of bleeding episodes in people with hemophilia A.

Your healthcare provider may give you ESPEROCT® when you have surgery.

### **Who should not use ESPEROCT®?**

You should not use ESPEROCT® if you

- are allergic to Factor VIII or any of the other ingredients of ESPEROCT®
- if you are allergic to hamster proteins

If you are not sure, talk to your healthcare provider before using this medicine.

Tell your healthcare provider if you are pregnant or nursing because ESPEROCT® might not be right for you.

### **What should I tell my healthcare provider before I use ESPEROCT®?**

You should tell your healthcare provider if you:

- Have or have had any medical conditions.
- Take any medicines, including non-prescription medicines and dietary supplements.
- Are nursing.
- Are pregnant or planning to become pregnant.
- Have been told that you have inhibitors to Factor VIII.

### **How should I use ESPEROCT®?**

Treatment with ESPEROCT® should be started by a healthcare provider who is experienced in the care of patients with hemophilia A.

ESPEROCT® is given as an infusion into the vein.

You may infuse ESPEROCT® 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 hemophilia treatment center or healthcare provider. Many people with hemophilia A learn to infuse the medicine by themselves or with the help of a family member.

Your healthcare provider will tell you how much ESPEROCT® to use based on your weight, the severity of your hemophilia A, and where you are bleeding. Your dose will be calculated in international units, IU.

### **Call your healthcare provider right away if your bleeding does not stop after taking ESPEROCT®.**

If your bleeding is not adequately controlled, it could be due to the development of Factor VIII inhibitors. This should be checked by your healthcare provider. You might need a higher dose of ESPEROCT® or even a different product to control bleeding. Do not increase the total dose of ESPEROCT® to control your bleeding without consulting your healthcare provider.

### **Use in children**

ESPEROCT® can be used in children. Your healthcare provider will decide the dose of ESPEROCT® you will receive.

### **If you forget to use ESPEROCT®**

If you forget a dose, infuse the missed dose when you discover the mistake. Do not infuse a double dose to make up for a forgotten dose. Proceed with the next infusions as scheduled and continue as advised by your healthcare provider.

### **If you stop using ESPEROCT®**

Do not stop using ESPEROCT® without consulting your healthcare provider.

If you have any further questions on the use of this product, ask your healthcare provider.

### **What if I take too much ESPEROCT®?**

Always take ESPEROCT® exactly as your healthcare provider has told you. You should check with your healthcare provider if you are not sure. If you infuse more ESPEROCT® than recommended, tell your healthcare provider as soon as possible.

### **What are the possible side effects of ESPEROCT®?**

#### **Common Side Effects Include:**

- rash or itching
- swelling, pain, rash or redness at the location of infusion

#### **Other Possible Side Effects:**

You could have an allergic reaction to coagulation Factor VIII products. **Call your healthcare provider right away or get emergency treatment right away if you get any signs of an allergic reaction, such as:** hives, chest tightness, wheezing, dizziness, difficulty breathing, and/or swelling of the face.

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

These are not all of the possible side effects from ESPEROCT®. Ask your healthcare provider for more information. You are encouraged to report side effects to FDA at 1-800-FDA-1088.

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

### **What are the ESPEROCT® dosage strengths?**

ESPEROCT® comes in five different dosage strengths. The actual number of international units (IU) of Factor VIII in the vial will be imprinted on the label and on the box. The five different strengths are as follows:

| Cap Color Indicator | Nominal Strength |
|---------------------|------------------|
| Red                 | 500 IU per vial  |
| Green               | 1000 IU per vial |
| Gray                | 1500 IU per vial |
| Yellow              | 2000 IU per vial |
| Black               | 3000 IU per vial |

Always check the actual dosage strength printed on the label to make sure you are using the strength prescribed by your healthcare provider.

### **How should I store ESPEROCT®?**

**Prior to Reconstitution** (mixing the dry powder in the vial with the diluent):

Protect from light. Do not freeze ESPEROCT®.

ESPEROCT® can be stored in refrigeration at 36°F to 46°F (2°C to 8°C) for up to 30 months until the expiration date stated on the label. During the 30 month shelf life, ESPEROCT® may be kept at room temperature (not to exceed 86°F/30°C) for up to 12 months, **or** up to 104°F (40°C) for no longer than 3 months.

If you choose to store ESPEROCT® at room temperature:

- Record the date when the product was removed from the refrigerator.
- Do not return the product to the refrigerator.
- Do not use after 12 months if stored up to 86°F (30°C) **or** after 3 months if stored up to 104°F (40°C) **or** the expiration date listed on the vial, whichever is earlier.

Do not use this medicine after the expiration date which is on the outer carton and the vial. The expiration date refers to the last day of that month.

#### **After Reconstitution:**

The reconstituted (the final product once the powder is mixed with the diluent) ESPEROCT® should appear clear and colorless without visible particles.

The reconstituted ESPEROCT® should be used immediately.

If you cannot use the reconstituted ESPEROCT® immediately, it must be used within 4 hours when stored at or below 86°F (30°C) or within 24 hours when stored in a refrigerator at 36°F to 46°F (2°C to 8°C). Store the reconstituted product in the vial.

Keep this medicine out of the sight and out of reach of children.

### **What else should I know about ESPEROCT® and hemophilia A?**

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

Revised: 10/2019

ESPEROCT® is a trademark of Novo Nordisk Health Care AG.

For Patent Information, refer to: <http://novonordisk-us.com/patients/products/product-patents.html>

**More detailed information is available upon request.** Available by prescription only.

Manufactured by:

Novo Nordisk A/S

Novo Allé

DK-2880 Bagsværd, Denmark

For information about ESPEROCT® contact:

Novo Nordisk Inc.

800 Scudders Mill Road

Plainsboro, NJ 08536, USA

1-800-727-6500

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## COVID-19 RESOURCES

As the nation responds to an outbreak of COVID-19, HFA is closely monitoring the situation and is evaluating the impact that it can have on the bleeding disorders community and our programming and events.

[www.hemophiliafed.org/news-stories/2020/04/coronavirus-covid-19-what-hfa-is-doing/](http://www.hemophiliafed.org/news-stories/2020/04/coronavirus-covid-19-what-hfa-is-doing/)

- Medical news, Industry news & product availability
- Patient care and Product Availability concerns; insurance coverage concerns
- Mental wellness, financial assistance, family/parent/education resources
- National, government and other patient links including CDC and WHO

Ohioans are facing new financial challenges as a result of the COVID-19 pandemic, and state agencies have a number of programs and policies in place to help. Check for info pertinent to Ohio: [www.coronavirus.ohio.gov](http://www.coronavirus.ohio.gov)

<https://coronavirus.ohio.gov/wps/portal/gov/covid-19/home>



# FAMOHIO CONFERENCE



FAMOHIO's priority has always been the health and safety of the bleeding disorders community. As the

COVID-19 pandemic unfolds, it is clear that we need to make the difficult decision to protect the health of our community and staff and cancel the in-person FAMOHIO conference this summer.

We are exploring options to possibly provide some virtual education in partnership with the 5 chapters in Ohio, as well as OBDC regarding Advocacy efforts later this year.

If you have any questions, please let us know. We hope each of you and your families are safe & healthy.

If you would like to be on FAMOHIO's email list for future updates please email [FAMOHIOInfo@gmail.com](mailto:FAMOHIOInfo@gmail.com).

[www.famohio.org](http://www.famohio.org) | [FAMOHIOInfo@gmail.com](mailto:FAMOHIOInfo@gmail.com) | 614-344-1075

## COMMUNITY CONNECTIONS

On February 20, eighteen SWOHF members attended Genentech's Interactive Workshop Program "The Science of Optimism—Staying Optimistic while Navigating Change." Our dinner was held at Figlio's Wood Fired Pizza in Kettering and hosted by Ami Seligman, RN, MHA, Genentech Hemophilia Community Clinical Educator. We were encouraged to view difficult circumstances as opportunities to build resilience. We enjoyed a fun family activity around our tables.



# HTC CORNER



In collaboration with Dayton Children's HTC, SWOHF has recently switched to a new provider for our Medical ID's. We are happy to announce our partnership with American Medical ID. They offer a great variety of quality products at a discount to Chapters. Additionally, their Customer Service is exceptional, their shipping is fast and their prices are significantly less than MedicAlert (our previous supplier).

Free products are included with every order: An emergency medical ID card, a small ID charm and an exclusive engraved rectangular "InCase" phone ID that easily attaches to your cellphone case or any flat object, such as a suitcase, briefcase or laptop.

SWOHF is grateful for grant funding and donations that facilitate these purchases on behalf of our Greater Dayton Bleeding Disorders Community. So when you go to the HTC for your next visit, you can view sample products available and complete a form to request a new bracelet or necklace according to Chapter guidelines.



[Phone not included]



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**SWOHF**  
SOUTHWESTERN OHIO  
HEMOPHILIA FOUNDATION

## CONTACT US

WE WANT TO HEAR FROM YOU!

### MISSION STATEMENT

SWOHF helps improve the quality of life for those affected by hemophilia, von Willebrand disease, and other bleeding disorders by providing support education, networking, advocacy, and services to individuals, their families and the community.

### EXECUTIVE DIRECTOR

Kay Clark

### DISCLAIMER

*The material provided in Factor Notes is for your general information only. SWOHF does not give medical advice or engage in the practice of medicine. SWOHF under no circumstances recommends particular treatment for specific individuals, and in all cases recommends that you consult your physician or treatment center before pursuing any course of treatment.*

Southwestern Ohio Hemophilia Foundation

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