FACTOR NOTES

BROUGHT TO YOU BY THE SOUTHWESTERN OHIO HEMOPHILIA FOUNDATION

HTC STAFF CHANGES

Dayton Children's Hemostasis and Thrombosis Center staff is happy to announce the addition of Melissa Tucker, RN, to the hemophilia team.

Melissa will assume Sandy Hibner's role as a hematology research nurse coordinator. Sandy will continue as a member of the team on a part-time basis until her retirement, which has not been officially announced. A new social worker is scheduled to begin orientation at the end of the month. More details will follow in the next newsletter!

2018
ISSUE #4

MEET MELISSA AT YOUR NEXT HTC VISIT!

"Hi All! My name is Melissa Tucker and I am excited to be working alongside of you to help better the lives of those individuals with hemophilia. I look forward to celebrating the day that a cure is found!

I graduated from Edison Community College in 2013 and began my career at Dayton Children's in the Almost Home Unit shortly thereafter. In 2016 I joined the Hematology/Oncology Clinic which was such a blessing as Pediatric Hematology/Oncology was my passion for becoming a nurse. Many of you may have seen me either in a clinic visit or if you have come in for an infusion as those have both been my primary roles up to this point.

Born and raised here in the great state of Ohio I am a big Ohio State football fan (O-H) and enjoy watching the games with my family. My husband Greg and I are raising our awesome children Logan, Gavin and Adison in Darke County, which is where I have spent the majority of my life.

After high school, I served proudly in the United States Air Force. I got my start in the medical field volunteering for the American Red Cross in the late '90s helping to facilitate blood drives at an Air Force Base in Germany. In the early 2000's, while working as a receptionist at a local pediatric practice, I started to appreciate the art of nursing. At that time, I also had the good fortune to meet an amazing nurse named Maureen. Maureen inspired me to become the best version of me, which led years later to becoming a nurse.

I personally believe we are all in charge of our own happiness. I sincerely look forward to the adventures and times ahead as I begin this journey with you."

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SAVE THE DATE

2019 CALENDAR OF SWOHF EVENTS

MARCH

Annual Meeting
Saturday, March 2
Beavercreek Golf Club
Beavercreek, OH
NOTE: New Location

OBDC Statehouse Day
Wednesday, March 13
Columbus, OH

MAY

Evening Out Casino Night
Friday, May 10
TBD

JUNE

Family Fest
June 14-16
Higher Ground Retreat Center
West Harrison, IN

AUGUST

FAMOHIO
August 2-4
Columbus, OH

Brad Miller Birdie Busters Golf Outing
Thursday, August 15
Beavercreek Golf Club
Beavercreek, OH

SEPTEMBER

Bleeding Disorders Awareness 5K
Saturday, September 21
Rice Field
Miamisburg, OH

OCTOBER

Fall Outing
Sunday, October 13
Young's Dairy
Yellow Springs, OH

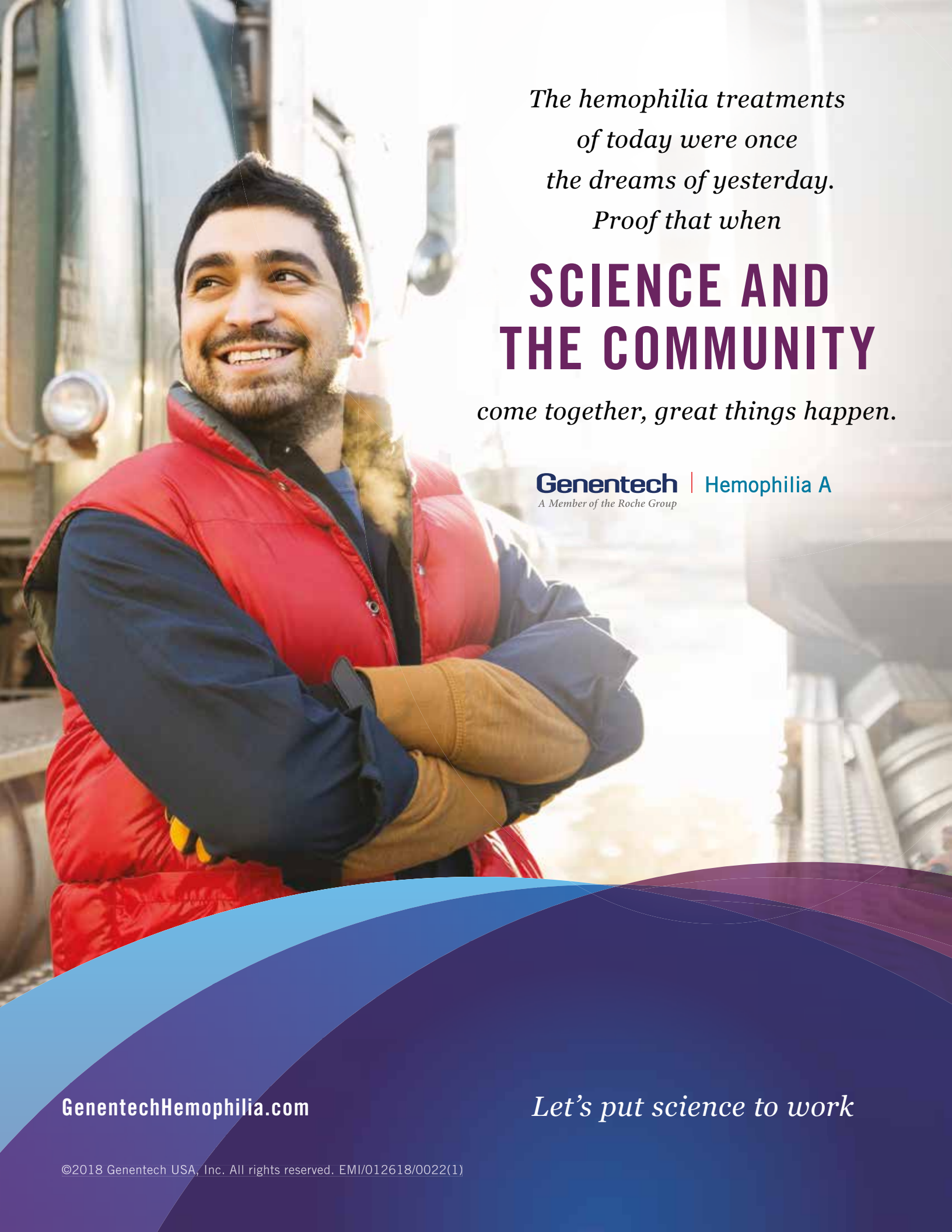
NOVEMBER

Women's Day Together
Saturday, November 9
TBD

If you are interested in representing SWOHF and participating in **Ohio Bleeding Disorders Council Statehouse Day**, Wednesday, March 13, please contact Kay in the SWOHF Office. Registration will open mid-January. Watch your email for more details!

2018 GOLF OUTING

August 16 was a great day of fun and community for 80 golfers who participated in this year's golf outing. Thanks to Dick Miller for his dedication to the success of this fundraiser. Our silent auction alone raised over $2000!



The hemophilia treatments of today were once the dreams of yesterday. Proof that when

SCIENCE AND THE COMMUNITY

come together, great things happen.

Genentech | Hemophilia A
A Member of the Roche Group

GenentechHemophilia.com

Let's put science to work

Finish Line Firsts for Awareness!

OTHER 1ST PLACE RESULTS BY AGE GROUPS (YOUNGEST TO OLDEST)

FEMALES:	*MALES:*
Nora & Liv Shellabarger	Alec Hill
Ashley Brown	Nathan Faulkner
Cassie Pence	Kevin Bostater
Becca Stammen	Ryan Bostater
Jen Rosson	Scott Gilbert
Margie Gitzinger	Grant Donaldson

OVERALL WINNERS: Mollie Courtney 22:52 (7.22 mile) & Jordan Sharp 23:17 (7.30 mile)

Thanks to all who came out in support of our **2018 Bleeding Disorders Awareness 5k**. It was a wonderful day for our 95 participants who ran, walked and even pushed strollers to show support of the SWOHF community and individual family members. Winners of the "You Make A Difference" awards were Julie Sampson and Carolyn Brown. Teams raising the most money were Team Shepard ($1331) and Team Trace ($839). Special thanks to Dena Shepard and her incredible crew of volunteers for all their work on this event! The T-shirts were especially awesome this year!

THANK YOU TO OUR 2018 SPONSORS

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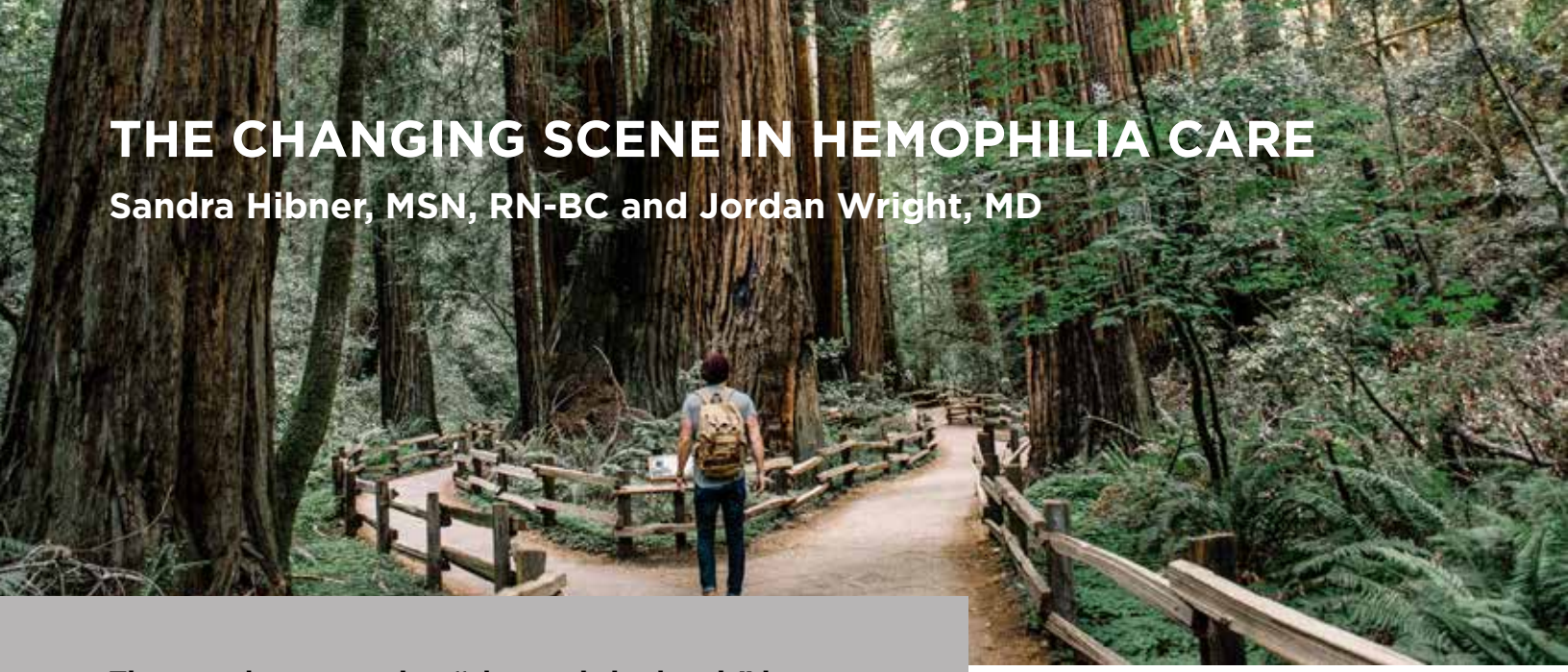

THE CHANGING SCENE IN HEMOPHILIA CARE

Sandra Hibner, MSN, RN-BC and Jordan Wright, MD

The popular expression "change is in the air" is particularly true in the world of hemophilia A and B, with and without inhibitors. Prevention of bleeding with prophylaxis and the opportunity to select extended half-life products remains a top choice therapy, however, two new exciting treatment modalities have also recently emerged. These therapies include new bypassing products and gene therapy.

As with any new medications or treatment choices, one must weigh the risks vs. the benefits. Both the regulatory agencies, known as the The Food and Drug Administration (FDA) in the United States and the European Medicines Agency (EMA) in Europe, require the completion of stringent research before any new products can be sold commercially. Unfortunately, some risks and benefits are not apparent until many years of use.

The new class of drugs for the treatment of hemophilia either replace function of missing clotting factor or bypass the need for missing clotting factor. There are several methods of treatment being developed including bispecific antibodies, tissue factor pathway inhibitor antagonists (TFPI), and anti-thrombin antagonists. All three of these treatments can be administered subcutaneously and have the potential to alter current concepts of prophylaxis in hemophilia.

dayton children's

New Medications

Emicizumab (Hemlibra®) is the first non-factor treatment approved by the FDA for use in patients with hemophilia A with or without inhibitors. Initially FDA was approved for patients with inhibitors in January 2018 and then for patients without inhibitors in October 2018. This bispecific monoclonal antibody mimics the actions of factor VIII by helping factor IX activate, which in turn leads to normal clotting.

This treatment does have a black box warning due to cases of thrombosis or thromboctic-microangiopathy(TMA). These complications occurred when used with high doses of the bypassing agent FEIBA (>100 units/kg/day).

Patients with high titer inhibitors, who have taken Emicizumab for a period of time, report minimal breakthrough bleeding, improved joint health, less pain, increased independence, and consequently an improved quality of life.

Patients also report the ease of administration has attributed to better adherence.

Both the tissue factor pathway inhibitor antagonists and the anti-thrombin antagonists remain in clinical trials. Both classes of drugs are being studied for treatment of patients with hemophilia A and hemophilia B, with or without inhibitors.

Gene Therapy
It is anticipated that gene therapy will be an option for treatment of both hemophilia A and B in the near future. Studies have demonstrated promising results with patients with severe hemophilia (<1% activity) achieving sustained levels of factor VIII or IX of 5-20% activity. Trials are using an adeno associated virus for transfection of the liver and have been limited to patients 18 years of age or older.

Many unanswered questions remain. Questions such as length of response, what to do with patients with inhibitors, can gene therapy be used in children, how to treat those who have antibodies to the viral vector, and cost are just a few.

Conclusion
The future looks bright, however, ongoing studies are paramount to ensure safety and efficacy of all new therapies. Immune Tolerance Induction (ITI) remains the only treatment available that has the possibility of eradicating inhibitors.

"As always, please feel free to discuss your hemophilia treatment we me and my staff at your comprehensive visit or sooner if you desire. I believe the best treatment for hemophilia is an individualized plan that encompasses both the needs of the patient and the recommendations of the physician. I look forward to discussing these new options as we continue to explore the world of hemophilia care together," says Dr. Wright.

Congratulations to SWOHF participants in the 17th Annual Gettin' in the Game Junior National Championship held in Phoenix, Arizona on Sept 28-30! You should be very proud of your achievement in representing SWOHF in this time-honored event. Dean Smith and George Carlson received our Chapter nominations for 2018.

Professional Golfer Perry Parker (pictured right with George) says: "Helping children and adolescents with bleeding disorders understand that physical activity can be fun and a part of their lives is important. I grew up thinking that I was the only kid with hemophilia. This event allows us to bring kids together to discuss issues and root for one another."

If you and your child (age 7-18 years) would like to be considered for SWOHF Chapter nomination, watch for more information in Factor Notes or via email in the spring.

UNLOCKING YOUR SELF-POTENTIAL

ONLY ADVATE® HAS 15 YEARS OF EXPERIENCE IN THE REAL WORLD AS A RECOMBINANT FACTOR VIII[1]

- Proven in a pivotal clinical trial to reduce the number of bleeding episodes in children and adults when used prophylactically[2]*
- Third-generation full-length molecule, similar to the factor VIII that occurs naturally in the body[1,2]

*Multicenter, open-label, prospective, randomized, 2-arm controlled trial of 53 previously treated patients with severe to moderately severe hemophilia A. Two different ADVATE prophylaxis regimens (standard, 20-40 IU/kg every 48 hours, or pharmacokinetic-driven, 20-80 IU/kg every 72 hours) were compared with on-demand treatment. Patients underwent 6 months of on-demand treatment before 12 months of prophylaxis.[2]

The market leader in hemophilia A treatment
(Based on 2016 data published July 2017)[3]

Learn more at ADVATE.com

ADVATE Important Information

What is ADVATE?

- ADVATE is a medicine used to replace clotting factor (factor VIII or antihemophilic factor) that is missing in people with hemophilia A (also called "classic" hemophilia).
- ADVATE is used to prevent and control bleeding in adults and children (0-16 years) with hemophilia A. Your healthcare provider (HCP) may give you ADVATE when you have surgery.
- ADVATE can reduce the number of bleeding episodes in adults and children (0-16 years) when used regularly (prophylaxis).

ADVATE is not used to treat von Willebrand disease.

DETAILED IMPORTANT RISK INFORMATION

Who should not use ADVATE?

Do not use ADVATE if you:

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

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

What should I tell my HCP before using ADVATE?

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 ADVATE passes into your milk and if it can harm your baby.
- Are or become pregnant. It is not known if ADVATE may harm your unborn baby.
- Have been told that you have inhibitors to factor VIII (because ADVATE may not work for you).

What important information do I need to know about ADVATE?

- You can have an allergic reaction to ADVATE. Call your HCP 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 ADVATE unless you have been taught by your HCP or hemophilia center.

What else should I know about ADVATE 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 ADVATE 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 ADVATE?

- Side effects that have been reported with ADVATE include: cough, headache, joint swelling/aching, sore throat, fever, itching, unusual taste, dizziness, hematoma, abdominal pain, hot flashes, swelling of legs, diarrhea, chills, runny nose/congestion, nausea/vomiting, sweating, and rash. Tell your HCP about any side effects that bother you or do not go away or if your bleeding does not stop after taking ADVATE.

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.

For additional safety information, please see Important Facts about ADVATE on the following page and discuss with your HCP.

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

References: 1. Grillberger L, Kreil TR, Nasr S, Reiter M. Emerging trends in plasma-free manufacturing of recombinant protein therapeutics expressed in mammalian cells. *Biotechnol J*. 2009;4(2):186-201. **2.** ADVATE Prescribing Information. **3.** The Marketing Research Bureau, Inc. The plasma proteins market in the United States. 2016.

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ADVATE
[Antihemophilic Factor (Recombinant)]

ADVATE
[Antihemophilic Factor (Recombinant)]

Important facts about

ADVATE [Antihemophilic Factor (Recombinant)]

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

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

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 ADVATE so that your treatment will work best for you.

What is ADVATE?

ADVATE is a medicine used to replace clotting factor (factor VIII or antihemophilic factor) that is missing in people with hemophilia A (also called "classic" hemophilia). The product does not contain plasma or albumin. Hemophilia A is an inherited bleeding disorder that prevents blood from clotting normally.

ADVATE is used to prevent and control bleeding in adults and children (0-16 years) with hemophilia A.

Your healthcare provider may give you ADVATE when you have surgery. ADVATE can reduce the number of bleeding episodes in adults and children (0-16 years) when used regularly (prophylaxis).

ADVATE is not used to treat von Willebrand disease.

Who should not use ADVATE?

You should not use ADVATE if you:

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

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

How should I use ADVATE?

ADVATE is given directly into the bloodstream.

You may infuse ADVATE 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 ADVATE by themselves or with the help of a family member.

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

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

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

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

You should tell your healthcare provider if you:

- Have or have had any medical problems.
- Take any medicines, including prescription and non-prescription medicines, 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 ADVATE passes into your milk and if it can harm your baby.
- Are pregnant or planning to become pregnant. It is not known if ADVATE may harm your unborn baby.
- Have been told that you have inhibitors to factor VIII (because ADVATE may not work for you).

What are the possible side effects of ADVATE?

You can have an allergic reaction to ADVATE.

Call your healthcare provider right away and stop treatment if you get a rash or hives, itching, tightness of the throat, chest pain or tightness, difficulty breathing, lightheadedness, dizziness, nausea or fainting.

Side effects that have been reported with ADVATE include:

cough	headache	joint swelling/aching
sore throat	fever	itching
unusual taste	dizziness	hematoma
abdominal pain	hot flashes	swelling of legs
diarrhea	chills	runny nose/congestion
nausea/vomiting	sweating	rash

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 ADVATE. You can ask your healthcare provider for information that is written for healthcare professionals.

What else should I know about ADVATE 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 ADVATE from working properly. Consult with your healthcare provider to make sure you are carefully monitored with blood tests for the development of inhibitors to factor VIII.

Medicines are sometimes prescribed for purposes other than those listed here. Do not use ADVATE for a condition for which it is not prescribed. Do not share ADVATE 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 ADVATE. The FDA approved product labeling can be found at www.ADVATE.com or 1-888-4-ADVATE.

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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RECORD-BREAKING ATTENDANCE AT SWOHF FALL OUTING

Sunday, October 7, was a gorgeous fall afternoon and we had a great turnout for our Annual Fall Outing at Young's Dairy. Over 200 individuals registered and attended! We heard from Dr. Jordan Wright, Dayton Children's HTC, and had a chance to chat with friends and win prizes. Many enjoyed putt-putt and the batting cages, along with other family activities. Thanks to all our industry partners who came out to support us. A fun time was had by all and, of course … ice cream!

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On your first visit to AmazonSmile *smile.amazon.com*, you need to select a charitable organization to receive donations from eligible purchases before you begin shopping. Search for Southwestern Ohio Hemophilia Foundation and make us your charity of choice. Amazon will remember your selection, and then every eligible purchase you make at *smile.amazon.com* will result in a donation.

SWOHF
Southwestern Ohio Hemophilia Foundation

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.

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

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