

Vital Link



...For Hoosiers Living with a Bleeding Disorder

December 2022

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Hemophilia of Indiana, Inc.

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2022 Year In Review

After a crazy couple of years, it was so nice to be mostly back to “normal in 2022! Hemophilia of Indiana was excited to have all events back to in-person events. The year started out great with the 2022 Hearts for Hemophilia “Fire & Ice” Gala. The event was a huge success and it was great to be able to move it back to the beginning of the year. Bowling for Bleeding Disorder was held in April to celebrate World Hemophilia Day and support the Judy Moore Scholarship Program. 10 teams participated and a lot of money was raised. The Course to a Cure Golf Outing was held in June and luckily the rain held off and it was great day on the links! One of the most exciting things for 2022 was siblings of affected campers were back at Camp Brave Eagle. In 2021, the difficult decision was made to only allow campers affected with a bleeding disorder to attend camp. Despite a night of thunder storms, a great time was had by all campers. The Doug Thompson Teen Leadership Camp was held in July. It was also an exciting year for Teen Camp this year as it was able to be held outside of the State of Indiana for the first time since before COVID and also included teen girls affected with a bleeding disorder. The teens had a great time zip lining, white water rafting, and a ton of other activities. The Annual Meeting was held in August followed by the Unite for Bleeding Disorders Walk. The Annual Meeting was a great weekend of education and community spirit. The Unite for Bleeding Disorders Walk was a huge success and we raised over \$50,000! The NHF Bleeding Disorders conference was also back in person and was held in Houston, TX. Scholarships were provided to Indiana families by Hemophilia of Indiana to attend the conference! Polo at Sunset was held the beginning of September and it was a beautiful evening watching polo and bringing awareness to the bleeding disorders community of Indiana. The THXRUN was another successful event and couldn't ask for better weather for the event! The Year End Educational event was held December 4th and it was widely attended and the kiddos and adults were all excited to get a visit from Santa! Hemophilia of Indiana is gearing up for 2023 and are excited to continue to celebrate and support the incredible bleeding disorders community of Indiana!

A Year in Review Photo Edition!





Indiana
Hemophilia
& Thrombosis
Center

Bleeding disorder care for a brighter future

For people with bleeding disorders, a healthier tomorrow starts with the best care today. IHTC is here to support all the members of our bleeding disorders community.

The IHTC is home to Indiana's experts in rare bleeding & blood disorders, including:
Hemophilia | HHT | HVLM | Thrombosis & Clotting | Sickle Cell Disease | von Willebrand Disease

The Indiana Hemophilia & Thrombosis Center (IHTC) provides advanced care for both adult and pediatric patients with rare bleeding and blood disorders. As Indiana's only federally recognized hemophilia treatment center, IHTC is one of the nation's largest HTCs, delivering innovative, multi-disciplinary care in Indianapolis and at outreach clinics across the state. Visit ihtc.org

Indiana Hemophilia & Thrombosis Center, Inc. | 8326 Naab Road | Indianapolis, IN 46260 | 877.CLOTTER

2022 Fitlivin THXRUN

The 14th Annual Fitlivin THXRUN was held on Thanksgiving morning. This year we had over 360 runners and walkers! The Fitlivin THXRUN was first started in the backyard of bleeding disorders community members Kasey and Matt Shade. As it grew over the years, Hemophilia of Indiana took over management of the run and continues to be a Thanksgiving tradition! There is a 1.5 mile and 4 mile course and a free Kids Run before the start of the Run. The weather was perfect for a Run and fun was had by all! Especially the runners that won a prize for carrying a pumpkin during the Run! Thank you to everyone that participated and especially our sponsors!



HEARTS FOR HEMOPHILIA



BLACK & WHITE GALA

SAVE
THE
DATE

January 27, 2023

HEMOPHILIA
OF INDIANA

Upcoming Educational Dinners:

Contact Angel DiRuzza at adiruzza@hoii.org to register.
Check out our Facebook (@HEMOINDY) page and website
calendar for more details on upcoming in person
educational dinners!

Topic: Hemgenix - Newly FDA Approved Gene Therapy Product

When: Tuesday, January 10, 2023

Where: Sullivan's Steakhouse
3316 E 86th St
Indianapolis, IN 46240

NOW APPROVED FOR ONCE-WEEKLY PROPHYLAXIS

BE READY FOR THE UNEXPECTED

ONCE-WEEKLY REBINYN® HELPS YOU KEEP FACTOR 9 LEVELS HIGHER FOR LONGER*

Timothy has severe hemophilia B and uses Rebinyn®.

Expect higher factor levels and bleed protection with once-weekly Rebinyn®.^b



With once-weekly Rebinyn®, adults and adolescents with hemophilia B can spend approximately 80% of their week with Factor 9 levels in the non-hemophilia range (greater than 40%).^b



in adults treated with Rebinyn® 40 IU/kg^c



in adolescents treated with Rebinyn® 40 IU/kg^c

Visit www.rebinyn.com to learn more about once-weekly Rebinyn®

^aRebinyn® achieved and maintained higher factor levels than recombinant Factor 9 based upon a phase 1 study comparing 25, 50, and 100 IU/kg doses of Rebinyn® to a 50 IU/kg dose of standard half-life recombinant Factor 9 in 7 adults and a 50 IU/kg dose of plasma-derived Factor 9 in 8 adults. For Rebinyn®, estimated average Factor 9 activity is adjusted to a dose of 50 IU/kg. Incremental recovery at 30 minutes (IR₃₀) and half-life were higher and longer with Rebinyn® than recombinant Factor 9 (IR₃₀ 0.0131 vs 0.0068 (IU/mL)/(IU/kg) and half-life 93 vs 19 hours). The clinical relevance of these pharmacokinetic differences is unknown.

Incremental Recovery: The increase in plasma concentration per IU/kg of factor administered.

Half-life: The time it takes for the level of factor in the blood to fall by half (50%).

^bData represent mean steady-state pharmacokinetic (PK) profiles from previously treated adolescent/adult patients with moderate-to-severe hemophilia B (N=9) taking repeated doses of Rebinyn® 40 IU/kg once weekly. Factor 9 levels were within the non-hemophilia range (greater than 40%) for 5.4 days (about 80% of the week).

^cBased on analysis using a 1-stage assay in patients (N=6) aged 18 and older, the half-life at steady state was 115 hours following once-weekly (40 IU/kg) dosing; in patients (N=3) aged 13 to 17, the half-life at steady state was 103 hours. Following single-dose administration (40 IU/kg) in the same patient population, the half-life was 83 hours (adults) and 89 hours (adolescents).

Indications and Usage

What is Rebinyn® Coagulation Factor IX (Recombinant), GlycoPEGylated?

Rebinyn® is an injectable medicine used to replace clotting Factor IX that is missing in patients with hemophilia B. Rebinyn® is used to treat, prevent, or reduce the frequency (number) of bleeding episodes in people with hemophilia B. Your healthcare provider may give you Rebinyn® when you have surgery. Rebinyn® is not used for immune tolerance therapy.

Important Safety Information

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

- Do not attempt to do an infusion yourself unless you have been taught how by your healthcare provider or hemophilia treatment center. Carefully follow your healthcare provider's instructions regarding the dose and schedule for infusing Rebinyn®.

Who should not use Rebinyn®?

Do not use Rebinyn® if you:

- are allergic to Factor IX or any of the other ingredients of Rebinyn®.
- are allergic to hamster proteins.

What should I tell my healthcare provider before using Rebinyn®?

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 plan to become pregnant.
- have been told you have inhibitors to Factor IX.

How should I use Rebinyn®?

- Rebinyn® is given as an infusion into the vein.
- Call your healthcare provider right away if your bleeding does not stop after taking Rebinyn®.
- Do not stop using Rebinyn® without consulting your healthcare provider.

What are the possible side effects of Rebinyn®?

- Common side effects include infusion site reaction (bruising, bleeding, swelling, pain, or redness), itching, and rash.
- Your body can also make antibodies called "inhibitors" against Factor IX, including Rebinyn®, which may stop Rebinyn® from working properly. Your healthcare provider may need to test your blood for inhibitors from time to time.
- Call your healthcare provider right away or get emergency treatment right away if you get, for example, any of the following signs of an allergic reaction: hives, chest tightness, wheezing, difficulty breathing, and/or swelling of the face.
- You may be at an increased risk of forming blood clots in your body, especially if you have risk factors for developing blood clots. Call your healthcare provider if you have chest pain, difficulty breathing, leg tenderness, or swelling.
- Animals given repeat doses of Rebinyn® showed Polyethylene Glycol (PEG) in certain cells in the brain. The potential human implications of these animal tests are unknown.

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

Rebinyn® is a prescription medication.

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.



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

Rebinyn® is a registered trademark of Novo Nordisk Health Care AG.

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rebinyn®
Coagulation Factor IX
(Recombinant), GlycoPEGylated

rebinyn®

Coagulation Factor IX (Recombinant), GlycoPEGylated

Brief Summary Information about:

REBINYN® Coagulation Factor IX (Recombinant), GlycoPEGylated

Rx Only

This information is not comprehensive.

- Talk to your healthcare provider or pharmacist
- Visit www.novo-pi.com/REBINYN.pdf to obtain FDA-approved product labeling
- Call 1-844-REB-INYN

Read the Patient Product Information and the Instructions For Use that come with REBINYN® before you start taking this medicine and each time you get a refill, as there may be new information.

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

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

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 REBINYN® so that your treatment will work best for you.

What is REBINYN®?

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

REBINYN® is used to treat, prevent, or reduce the frequency (number) of bleeding episodes in people with hemophilia B.

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

Who should not use REBINYN®?

You should not use REBINYN® if you

- are allergic to Factor IX or any of the other ingredients of REBINYN®
- 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 REBINYN® might not be right for you.

What should I tell my healthcare provider before I use REBINYN®?

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

How should I use REBINYN®?

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

REBINYN® is given as an infusion into the vein.

You may infuse REBINYN® 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 B learn to infuse the medicine by themselves or with the help of a family member.

Your healthcare provider will tell you how much REBINYN® to use based on your weight, the severity of your hemophilia B, 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 REBINYN®.

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

Use in children

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

If you forget to use REBINYN®

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 speak to your healthcare provider if you have any questions or concerns.

If you stop using REBINYN®

Do not stop using REBINYN® 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 REBINYN®?

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

What are the possible side effects of REBINYN®?

Common Side Effects Include:

- infusion site reaction (bruising, bleeding, swelling, pain, or redness)
- itching
- rash

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

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

You may be at an increased risk of forming blood clots in your body, especially if you have risk factors for developing blood clots. Call your healthcare provider if you have chest pain, difficulty breathing, leg tenderness or swelling.

These are not all of the possible side effects from REBINYN®. 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 REBINYN® dosage strengths?

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

Cap Color Indicator	Nominal Strength
Red	500 IU per vial
Green	1000 IU per vial
Yellow	2000 IU per vial
Dark Gray	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 REBINYN®?

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

Store in original package in order to protect from light. Do not freeze REBINYN®.

REBINYN® vials can be stored in the refrigerator (36-46°F [2°C-8°C]) for up to 24 months until the expiration date, or at room temperature (up to 86°F [30°C]) for a single period not more than 6 months.

If you choose to store REBINYN® at room temperature:

- Note the date that the product is removed from refrigeration on the box.
- The total time of storage at room temperature should not be more than 6 months. Do not return the product to the refrigerator.
- Do not use after 6 months from this date 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) REBINYN® should appear clear without visible particles.

The reconstituted REBINYN® should be used immediately.

If you cannot use the reconstituted REBINYN® immediately, it should be used within 4 hours when stored at or below 86°F (30°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 REBINYN® and hemophilia B?

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

For more information about REBINYN®, please call Novo Nordisk at 1-844-REB-INYN.

Revised: 08/2022

REBINYN® is a trademark of Novo Nordisk A/S.

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

Manufactured by:
Novo Nordisk A/S
Novo Allé, DK-2880 Bagsværd, Denmark

More detailed information is available upon request.

Available by prescription only.

For information about REBINYN® contact:
Novo Nordisk Inc.
800 Scudders Mill Road
Plainsboro, NJ 08536, USA

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Year End Education Event

The 2023 Year End Education Event was held Sunday, December 4 at The Wellington Fishers and Banquet Conference Center. Over a 100 members of the bleeding disorders community were able to get together with their fellow community members for education and to celebrate the holiday season. There were crafts for the kids as well as a special visitor from the North Pole!

Thank you to our 2022 Year End Education Event Sponsors!



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Important travel tips for people with bleeding disorders

With spring break and summer trips ahead, make plans for a safe and enjoyable time away



General Preparations

- **Call the IHTC for a travel letter and always carry it with you on your trip.** A travel letter includes your condition, type of medicine or clotting factor used, dosage, and the IHTC's contact info: 877-256-8837.
- **Find the contact info of the Hemophilia Treatment Center closest to your travel destination in case of an emergency.** Scan the QR code below to find an HTC near your destination, or call the IHTC for help.
- **Plan ahead and pack all supplies needed for the trip a few days ahead of time.** Carry enough supplies to avoid problems during your trip.

Preparations for Flying

- **Pack a prescription from your provider in your carry-on luggage when flying.** Medicines should have their original label attached. Your clotting factor products and supplies need to be in your carry-on luggage to avoid damage or loss.
- **Call the airline two days before your travel** to see if they have specific rules about flying with medicine. You can also call TSA Cares, a hotline for those with disabilities or medical conditions (1-855-787-2227).
- **Scan the QR codes below** for info from the U.S. Department of State about international travel. Their STEP Program also allows you to register your international travel so they can assist you in an emergency.

Emergency care tips

- **Call the IHTC first**
- **Take these items with you to the Emergency Department (ED):**
 - Your factor concentrate
 - A list of medicines you take regularly
 - Medical records
 - Medical insurance info
 - Special medical supplies (i.e., port needles)
 - Patience
- **Ask the ED staff if they have talked to your IHTC provider before you are treated**
- **Provide the ED staff with info about your disorder and explain your specific needs**
- **Stay calm and treat the staff as you wish to be treated**
- **Remember you will need pre-treatment with factor concentrate before most invasive procedures (like stitches or surgery). Routine blood draw is an exception that does not need pre-treatment.**
- **ED visits take several hours**
- **If you have a bad experience, please report this to the IHTC**

Helpful Links

Scan these QR codes for more information



Find an HTC
near your
destination



U.S. Department
of State
International
Travel Info



Smart Travel
Enrollment
Program
(STEP)



Children and Anxiety

Anxiety diagnoses are on the rise. Here's how to recognize symptoms in your child.

It's normal for babies and toddlers to have separation anxiety when they're away from their parents, but these days a lot of older kids are dealing with all kinds of anxiety.

The 2018–2019 National Survey of Children's Health revealed that the number of children and adolescents who were diagnosed with anxiety increased by 27 percent from 2016 to 2019. By 2020, the year the COVID-19 pandemic began, **5.6 million kids (9.2 percent)** had been diagnosed with anxiety problems. What's more, there's **evidence** that children with hemophilia are prone to anxiety disorders and depression.

Children with anxiety have a greater risk of developing an anxiety disorder or depression as an adult, which is one of the reasons why the **U.S. Preventive Services Task Force** recently recommended that all children ages 8 and older be screened for anxiety.

Signs of Anxiety in Children

Anxiety in children often presents as fear or worry, but it can also make children irritable and angry. Other symptoms of anxiety in children may include trouble sleeping and physical symptoms such as fatigue, headaches, and stomachaches.

In addition to the separation anxiety that very young children often experience, there are several other types of anxiety in children, according to the American Academy of Child and Adolescent Psychiatry:

- Phobias involve an extreme fear about a specific thing or situation (such as dogs or heights). These fears can cause significant distress and interfere with usual activities.
- Social anxiety involves fears of meeting or talking to people, and avoidance of social situations.
- Panic disorder causes repeated episodes of sudden, unexpected, intense fear that comes with symptoms such as heart pounding, trouble breathing, or feeling dizzy, shaky, or sweaty.
- Generalized anxiety disorder causes constant worries or concerns about family, school, friends, or activities. These worries may include repetitive unwanted thoughts (obsessions) or actions (compulsions). Children with generalized anxiety disorder are often afraid of embarrassment or making mistakes and have low self-esteem.

Treatment for Children's Anxiety

If you suspect your child may have an anxiety disorder, talk to their primary care provider or the social worker at your hemophilia treatment center, who may refer you to a child and adolescent psychiatrist or another mental health professional. Most children with anxiety disorders can be successfully treated with psychotherapy, although severe anxiety may also require medication.

HEMOPHILIA
OF INDIANA
2023
CALENDAR OF EVENTS

Hearts for Hemophilia Gala: *Union Station*: January 27

Bowling for Bleeding Disorders, *Pinheads*: March 25

World Hemophilia Day: April 17

UNITE for Bleeding Disorders Walk *Ft. Harrison State Park*: May 20

Course to a Cure Golf Outing, *Maple Creek Golf & Country Club*: June 9

Camp Brave Eagle, *Camp Crosley*: June 11-16

Annual Meeting, *Crowne Plaza Hotel - Indianapolis Airport*: Aug. 12-13

NHF Bleeding Disorder Conference, *Washington DC*: August 17-19

Thanksgiving Day Run, *Dillon Park*: November 23

Year End Educational Program *The Wellington Fishers*: December 2

Our mission:

Hemophilia of Indiana is dedicated to empowering the bleeding disorders community through education and support, while advocating access to quality care and product safety.

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*The material provided in Vital Link is only for general information purposes. HoII does not give medical advice or engage in the practice of medicine. HoII recommends in all cases that you consult your physician or HTC before pursuing any course of treatment.

Mark your Calendars!

- 2023 Hearts for Hemophilia Gala - January 27th
- 2023 Bowling for Bleeding Disorders - March 25
- 2023 Unite for Bleeding Disorders Walk - May 20

Call our office @ (317) 570-0039 or email Kristy McConnell @ kmccconnell@hoii.org if you would like to get involved in any of our events!

- Check out our social media pages for updates!!!

