

Alhemo®
concizumab-mtci
injection | 60 mg | 150 mg | 300 mg pens

More than a pen—

YOUR EVERYDAY BLEED PROTECTION^a

First prophylaxis treatment in a prefilled, subcutaneous pen to prevent or reduce frequency of bleeding episodes in adults and children 12 years of age and older with hemophilia B with inhibitors or hemophilia A with inhibitors

^aIt is important to follow the daily dosing schedule of Alhemo® to stay protected against bleeding.



Celebrating
35+
YEARS
serving the hemophilia
with inhibitors community



Needles provided separately and may require a prescription in some states.

Important Safety Information

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

- **It is important to follow the daily dosing schedule of Alhemo® to stay protected against bleeding.** This is especially important during the first 4 weeks of treatment to make sure a correct maintenance dose is established. Use Alhemo® exactly as prescribed by your healthcare provider (HCP). **Do not** stop using Alhemo® without talking to your HCP. If you miss doses or stop using Alhemo®, you may no longer be protected against bleeding
- **Your HCP may prescribe bypassing agents during treatment with Alhemo®.** Carefully follow your HCP's instructions regarding when to use on-demand bypassing agents, and the recommended dose and schedule for breakthrough bleeds

Royal lives with hemophilia B with inhibitors, uses Alhemo®, and is an employee of Novo Nordisk.

Please see Important Safety Information throughout.
Please see [Prescribing Information](#) and [Medication Guide](#).



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Living with hemophilia B with inhibitors

You may face **serious challenges and potential risks** with limited treatment options

Bleeds can lead to **joint damage**, so having **preventative treatment is essential**

In a real-world study of people with hemophilia, including hemophilia B with inhibitors:

Median Annual Bleed Rate



Bleeds per year
when using bypassing
agents on demand
(16 people)



Bleeds per year
when using bypassing
agents as prophylaxis
(15 people)

This study looked at past records of patients with hemophilia, including of 31 male adults and adolescents aged 12 years and older who have hemophilia B with inhibitors, of any severity. It aimed to learn more about their everyday needs. In the study, 16 of them used bypassing agents only when a bleed happened (on demand), and on average, they used this treatment for about 9 years (111 months). The other 15 people used these treatments as a preventive prophylaxis, doing so for around 7 years (85 months) on average. The study also looked at how often bleeds happened each year (median bleeds per year).

Until now, your **only option** for bleed protection has **left you vulnerable to**



Severe allergic reactions
(anaphylaxis)



Numerous IV administration
steps including mixing



Multiple IV infusions
per week for prophylaxis

You deserve daily bleed protection with a treatment
MADE WITH YOUR CHALLENGES IN MIND

IV=intravenous.

Please see Important Safety Information throughout.
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For people living with hemophilia with inhibitors who previously used BPAs on demand—

Transformative administration with a prefilled pen^{a,b}

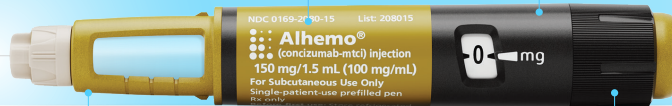
Subcutaneous administration (no need for vein access)

Ultra-thin needle^c

- NovoFine® Plus 32G 4 mm needles are designed for less pain and increased injection comfort
- Needle as thin as 2 human hairs

Portable and ready to use: Prefilled, no mixing required^d

Room temperature stable up to 4 weeks^d



Low injection volume

- (Example: 0.14 mL per 0.2 mg/kg dose for 70 kg person using the gold 150 mg/1.5 mL pen)

Dose selector

- Dial up to 80 dose increments
- Can be turned in either direction to adjust dose

Push-button technology

- Does not extend regardless of dose



No IV infusions



No mixing



No vials



No refrigeration required^d
(up to 4 weeks after first use)

Administration designed to fit **your** lifestyle^{a,b}

Novo Nordisk pen device used for
15 YEARS
in other conditions

“

I like the once-daily dosing because of the **small needle** and low dosage volume.

”

—Royal lives with hemophilia B with inhibitors, uses Alhemo®, and is an employee of Novo Nordisk.

98% rated the pen **easy to use**
(78 people)

97% rated the pen **easy to learn to use**
(78 people)

99% rated the pen **easy to store**
(76 people)

Easy=easy or very easy.

Less than
90 seconds
to prepare
and administer



Read **Instructions for Use** for full administration instructions.

Study design: In a study about using Alhemo® pen, 80 patients with hemophilia A or B, with or without inhibitors, using factor replacement or Factor 8 mimetic therapy, and caregivers were included. The main purpose was to determine whether the Alhemo® pen-injector is easy to learn how to use and easy to use. After training, people prepared and performed a single injection into an injection pad or dummy. Time for training, preparation, injections, and number of complete injections were assessed. Participants evaluated handling using a questionnaire. Response scale included the following choices: very difficult, difficult, neither difficult or easy, easy, very easy. Limitations of this study: this study may not be the same as the true experience of at-home use. In addition, it may be difficult for people to rate the pen based on 1 practice injection.

Important Safety Information (cont'd)

Do not use Alhemo® if you are allergic to concizumab-mtci or any of the ingredients in Alhemo®.

Before using Alhemo®, tell your HCP about all of your medical conditions, including if you:

- Have a planned surgery. Talk to your HCP about when to stop using Alhemo® and when to start it again if you have a planned surgery

^aRead the Instructions for Use for information about how to prepare and inject Alhemo®, and how to properly throw away used pens and needles. Your healthcare provider should show you or your caregiver how to use Alhemo® before you use it for the first time.

^bAfter the dose counter is at “0,” count slowly to 6 while the needle is still in your skin.

^cNeedles provided separately and may require a prescription in some states. A new needle is required for each injection.

^dStore in refrigerator before first use. After first use, Alhemo® can be stored at room temperature below 86 °F (30 °C) or in a refrigerator at 36 °F to 46 °F (2 °C to 8 °C) for up to 4 weeks.

BPAs=by-passing agents; IV=intravenous.

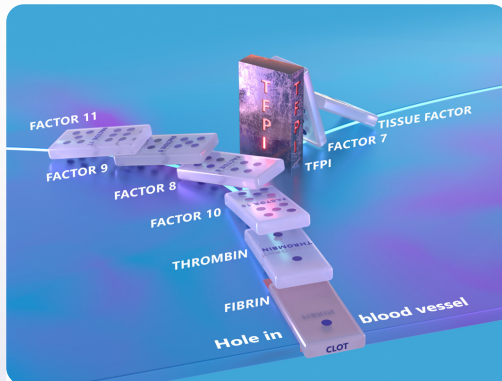
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concizumab-mtci
injection | 60 mg | 150 mg | 300 mg pens

Alhemo® is an **innovative approach** to preventing bleeds in **hemophilia B with inhibitors**

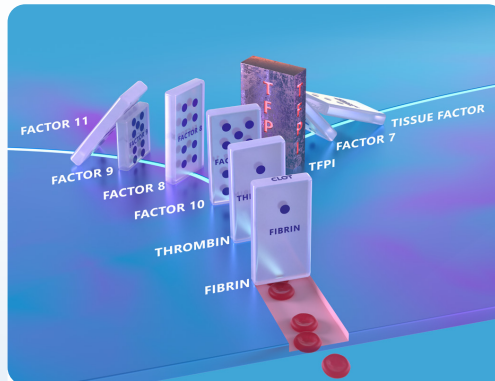
The clotting cascade is a series of steps, like a domino effect, where each domino represents a different clotting protein. **When the dominoes fall properly, clotting occurs:**



Clotting cascade without hemophilia

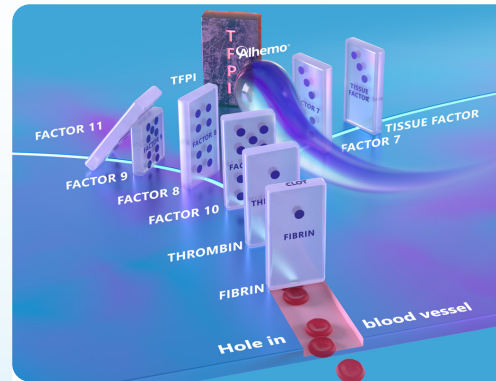
Factor 9 is part of the clotting cascade that falls onto other dominoes to form clots and prevent bleeding.

A protein called tissue factor pathway inhibitor, or TFPI, is also part of the process. It blocks the rest of the cascade's dominoes so there is not too much clotting.



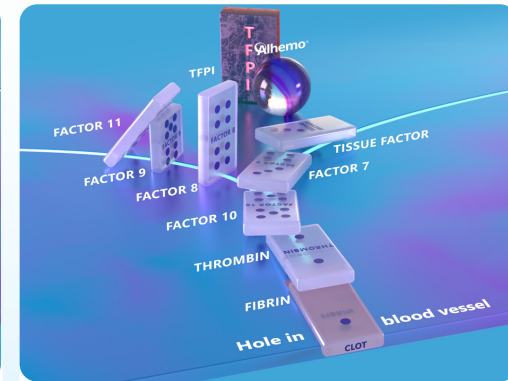
Clotting cascade in hemophilia B with inhibitors

In hemophilia B with inhibitors, the Factor 9 domino cannot fall onto the next domino, and TFPI still blocks the dominoes from falling on the other side of the cascade. When the dominoes do not fall, clots will not form, and bleeding may occur.



How Alhemo® works

Alhemo® stops TFPI from blocking the dominoes, so they can continue to fall, even without Factor 9 and with inhibitors.



Bleed prevention

As a result, the domino cascade can be completed and a clot can form.

Alhemo® helps keep blood in balance

- ✓ Helps the body create the right amount of thrombin
- ✓ Keeps thrombin levels consistent without peaks and troughs
- ✓ Works fast and exits the body quickly in 4 days*

Alhemo® works even when Factor 9 inhibitors are present

Important Safety Information (cont'd)

Before using Alhemo®, tell your HCP about all of your medical conditions, including if you (cont'd):

- Are pregnant, breastfeeding, or plan to become pregnant or to breastfeed. It is not known if Alhemo® may harm your unborn baby or if Alhemo® passes into your breast milk
- Your HCP may do a pregnancy test before you start treatment with Alhemo®.
- **Females who are able to become pregnant**, talk to your HCP about using effective birth control (contraception) methods during treatment with Alhemo® and for 7 weeks after ending treatment

Tell your HCP about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and supplements.

It's important to take Alhemo® daily, especially during the first 4 weeks, to ensure you get the correct maintenance dose and stay protected from bleeding. Always use Alhemo® exactly as prescribed. Do not stop or miss doses without first consulting your healthcare provider, as this may reduce your protection against bleeding.

To find the right maintenance dose for you, your provider will check Alhemo® levels in your blood. Additional blood tests may be done during treatment.

*After your Day 1 loading dose, the amount of Alhemo® builds up in the body to a stable amount around Day 4, and remains stable with daily maintenance doses. If you stop Alhemo®, 90% of it is expected to leave the body by the end of approximately 4 days after the last dose. The time for 50% of drug to leave the body is approximately 1 day.

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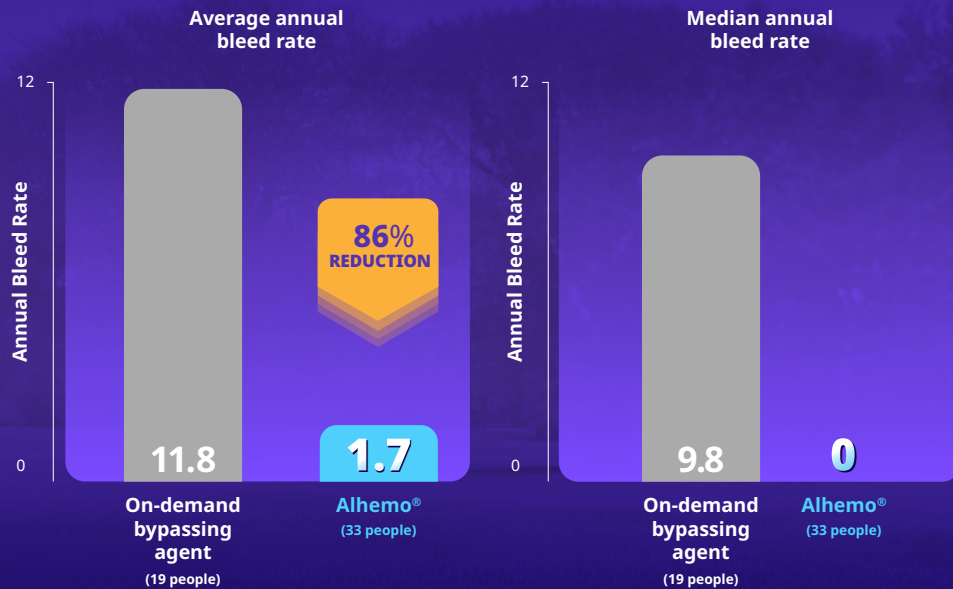


Results from a clinical trial with people who have hemophilia B with inhibitors or hemophilia A with inhibitors

Powerful bleed protection

Primary study results:

Treated spontaneous and traumatic bleeds



Clinical study of Alhemo® included people ages 12 years and older who had hemophilia B with inhibitors (53 people) and hemophilia A with inhibitors (80 people) who were treated with either bypassing agents on demand (at least 24 weeks) or Alhemo® once-daily prophylaxis (at least 32 weeks).

Discover lower target joint bleed rate and more bleed-free patients

88% lower in target joint bleed rate^a

Supportive secondary study result. Average target joint annual bleed rate of 0.1 with Alhemo® (33 people) vs 1.1 with no prophylaxis (19 people)

64% had zero bleeds^b

in 24 weeks for people on Alhemo® prophylaxis (21 people) vs 10.5% for no prophylaxis (2 people)
Additional assessment study result

“ I can't remember the last time I had a bleed. ”
—Royal

Individual results may vary. It is important to follow the daily dosing schedule of Alhemo® to stay protected against bleeding.

^aTreated target joint bleeds.

^bPatients with zero treated bleeds within first 24 weeks.

Important Safety Information (cont'd)

What are the possible side effects of Alhemo®?

Alhemo® may cause serious side effects, including:

- **Blood clots (thromboembolic events).** Alhemo® may cause blood clots to form in blood vessels, such as in your arms, legs, heart, lung, brain, eyes, kidneys, or stomach. You may be at risk for getting blood clots if you use high or frequent doses of factor products or bypassing agents to treat breakthrough bleeds, or if you have certain conditions. Get medical help right away if you have any signs and symptoms of blood clots, including: swelling, warmth, pain, or redness of the skin; headache; trouble speaking or moving; eye pain or swelling; sudden pain in your stomach or lower back area; feeling short of breath or severe chest pain; confusion; numbness in your face; and problems with your vision

Royal lives with hemophilia B with inhibitors, uses Alhemo®, and is an employee of Novo Nordisk.



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Royal lives with hemophilia B with inhibitors, uses Alhemo®, and is an employee of Novo Nordisk.

Safety confirmed in multiple clinical trials

320 people in clinical trials,
including 133 males with hemophilia with inhibitors

320 males with hemophilia A with and without inhibitors and hemophilia B with and without inhibitors received at least one dose of Alhemo® as routine prophylaxis. 52 people with inhibitors were previously treated with on demand therapy and were randomized to receive on demand treatment with bypassing agents (19 people) or Alhemo® prophylaxis (33 people).

0 thromboembolic events
in the clinical trial of people with hemophilia with inhibitors, after trial restart*

Alhemo® may cause blood clots to form in blood vessels, such as in your arms, legs, heart, lung, brain, eyes, kidneys, or stomach. You may be at risk for getting blood clots during treatment with Alhemo® if you use high or frequent doses of factor products or bypassing agents to treat breakthrough bleeds, or if you have certain conditions. Get medical help right away if you have any signs and symptoms of blood clots, including: swelling, warmth, pain, or redness of the skin; headache; trouble speaking or moving; eye pain or swelling; sudden pain in your stomach or lower back area; feeling short of breath or severe chest pain; confusion; numbness in your face; and problems with your vision

NO routine liver monitoring required

NO boxed warning

All bypassing agents can be used to treat breakthrough bleeds

Alhemo® does not treat bleeds. Your healthcare provider may prescribe a bypassing agent to use if you experience a breakthrough bleed.

Follow your healthcare provider's instructions regarding when to use on-demand bypassing agents and the recommended dose and schedule for breakthrough bleeds.

In the randomized arms of the clinical trial of people with inhibitors, injection site reactions were the most common adverse reactions, reported in 6 out of 33 people (18%) using Alhemo®, followed by hives, reported in 2 out of 33 people (6%).

Majority of injection site reactions were mild.

An allergic reaction in 1 patient (3%) led to stopping Alhemo® treatment.

*The explorer7 and explorer8 clinical trials were temporarily paused because 3 patients experienced 5 nonfatal TEs. In response, a plan was put in place that included deploying a laboratory developed test to measure concizumab-mtci levels in order to individualize dosing, as well as guidance around how to treat breakthrough bleeds.

†Should be performed before administering next scheduled dose.

TE=thromboembolic event.

Personalized dosing for you

Day 1

- You will inject a larger dose (a loading dose) of Alhemo® on your first day of treatment
- Your dose will be based on your weight: 1 mg/kg

Day 2+†

- Your dose will now be 0.2 mg/kg 1 time per day until you take a blood test

Day 28 (4 weeks after starting Alhemo®)

- To determine the right maintenance dose, you will take the blood test, which will show how much Alhemo® is in your body†
- Your healthcare provider may do additional blood tests during treatment with Alhemo®

It is important to follow the daily dosing schedule of Alhemo® to stay protected against bleeding, especially during the first 4 weeks of treatment, to help establish your maintenance dose.

If you miss a dose during the first 4 weeks of treatment, contact your healthcare provider right away. Your healthcare provider will tell you how much Alhemo® to inject.

If you miss doses, or stop using Alhemo®, you may no longer be protected against bleeding.

Did you know ?

Alhemo® has a test that measures the amount of concizumab-mtci in your blood? This allows your HCP to prescribe the dose that fits your body's needs.

Prepare for your laboratory test

Schedule your blood draw appointment and confirm its location—which may not be at your doctor's office.

Wait until after the blood draw to take your daily dose of Alhemo® on the day of your test.

Important Safety Information (cont'd)

What are the possible side effects of Alhemo®?

Alhemo® may cause serious side effects, including:

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Administration designed with **you in mind**

In a device-handling study of the Alhemo® pen involving 44 adults and 21 adolescents with hemophilia A or B, with or without inhibitors, as well as 15 caregivers, participants were trained and then practiced a simulated injection using a pad or dummy. They then shared their experience through a questionnaire. Nearly all participants, 78 people (98%), said the Alhemo® pen was easy or very easy to use, and on average, it took just 1 minute and 21 seconds to complete an injection. These results are based on a simulated setting and may not fully reflect at-home use.

Read the **Instructions for Use** for information about how to prepare and inject Alhemo®, and how to properly throw away used pens and needles. Your healthcare provider should show you or your caregiver how to use Alhemo® before you use it for the first time.

Alhemo® is given as an **injection under the skin** (subcutaneous injection) by you or a caregiver.

Alhemo® is administered **once daily**.

**PREP
ADMINISTER
PROTECT**

...less than
90 seconds!

Inject in
~6 seconds^b



1. Check Alhemo® pen

2. Attach new needle



3. Prime before each dose

Dial 1 marking to test flow before each dose.

4. Select dose



5a. Prepare injection site

5b. Inject Alhemo®^{a,b}



6. Remove needle

7. Recap pen

3 pen options,
each contains multiple
doses of Alhemo®



1 gold label pen (150 mg/1.5 mL)
has about **10 days of daily Alhemo® treatment**:
10 days of 0.2 mg/kg daily
maintenance treatment for a
patient weighing 154 lb (70 kg).

Alhemo® is recommended to be used with NovoFine® and NovoFine® Plus 32G 4 mm injection needles.

Remember to:

Rotate
injection sites daily.

Always
use a new needle
for each injection.

Never share Alhemo®
pens and needles with another
person, even if the needle is changed.

^aYou can inject in the skin of your stomach area (abdomen) at least 2 inches from your belly button (navel) or your upper legs (thigh). Change (rotate) your injection site with each injection every day. Do not use the same site for each injection. Do not inject into skin that is tender, bruised, red or hard, or areas where there are moles, scars, or stretch marks.

^bAfter the dose counter is at "0," count slowly to 6 while the needle is still in your skin.

Important Safety Information (cont'd)

What are the possible side effects of Alhemo®? (cont'd)

Alhemo® may cause serious side effects, including (cont'd):

• **Allergic reactions.** Alhemo® can cause allergic reactions, including redness of the skin, rash, hives, itching, and stomach-area (abdominal) pain. Stop using Alhemo® and get emergency medical help right away if you develop any signs or symptoms of a severe allergic reaction, including: itching on large areas of skin; trouble swallowing; wheezing; pale and cold skin; dizziness due to low blood pressure; redness or swelling of lips, tongue, face, or hands; shortness of breath; tightness of the chest; and fast heartbeat

The most common side effects of Alhemo® include: bruising, redness, bleeding, or itching at the site of injection, and hives. These are not all the possible side effects of Alhemo®. Call your doctor for medical advice about side effects.

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Alhemo® offers innovative administration

Not intended to be a comparison of efficacy or safety

Select administration features	Alhemo® ^a	Nonfactor therapy that reduces antithrombin ^c	On-demand bypassing agents
Prefilled pen device for all doses	✓	✗	✗
Low range (≤0.5 mL) of injection volume ^b	✓ 0.14 mL to 0.35 mL	✓ 0.1 mL to 0.5 mL	✗ 5.25 mL to 105 mL
Smallest needle size (higher gauge number = thinner needle)	✓ 32G	✗ 27G	✗ 23G to 25G suggested
No venous access needed	✓	✓	✗
Dosage schedule	Daily	Once every 1 to 2 months	As needed for bleeding episodes
Stable at room temperature	✓ Store at room temperature below 86 °F for up to 4 weeks after first use	✓ Store at room temperature (59 °F to 86 °F) for a single period of up to 3 months for pen	✓ Store from 36 °F to 86 °F ^d

^aRead the Instructions for Use for information about how to prepare and inject Alhemo®, and how to properly throw away used pens and needles. Your healthcare provider should show you or your caregiver how to use Alhemo® before you use it for the first time.

^bFor a patient weighing 70 kg, on Alhemo® 0.2 mg/kg, the volume to inject ranges from 0.14 mL to 0.35 mL, depending on pen size. For a patient weighing 70 kg, a single infused dose of NovoSeven® RT for a joint bleed (90 mcg/kg) is 6.3 mL. For a patient weighing 70 kg, a single infused dose of SEVENFACT® for a joint bleed (75 mcg/kg) is 5.25 mL. For a patient weighing 70 kg, a single infused dose of FEIBA® for a joint bleed (75 U/kg) is 105 mL. Qfitlia® volume to inject is 0.5 mL for a 50 mg dose, 0.2 mL for a 20 mg dose, and 0.1 mL for a 10 mg dose.

^cAntithrombin is a protein in the blood that prevents the formation of clots.

^dNovoSeven® RT and FEIBA® can be stored at 36 °F to 77 °F. SEVENFACT® can be stored at 36 °F to 86 °F.

Important Safety Information

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- **It is important to follow the daily dosing schedule of Alhemo® to stay protected against bleeding.** This is especially important during the first 4 weeks of treatment to make sure a correct maintenance dose is established. Use Alhemo® exactly as prescribed by your healthcare provider (HCP). **Do not** stop using Alhemo® without talking to your HCP. If you miss doses or stop using Alhemo®, you may no longer be protected against bleeding
- **Your HCP may prescribe bypassing agents during treatment with Alhemo®.** Carefully follow your HCP's instructions regarding when to use on-demand bypassing agents, and the recommended dose and schedule for breakthrough bleeds

Do not use Alhemo® if you are allergic to concizumab-mtci or any of the ingredients in Alhemo®.

NovoCare®—comprehensive support for your journey



Savings offer—copay assistance

If you are eligible and have commercial insurance, you could pay as little as \$0 for a 30-day supply of your medication, with a maximum benefit of up to [\$15,000] per year.^f



Dedicated patient liaisons

Our caring team is here to support you every step of the way.

As your primary point of contact, they will:

- Call to introduce you to our program
- Help you understand your insurance benefits and assist with enrolling in savings offers
- Arrange your device training, either in person or virtually, to suit your needs
- Provide ongoing reminders for your lab test and medication refills



Interim drug

For eligible patients on therapy who experience a gap in their commercial insurance coverage.^f



Patient assistance program

If you qualify, our Patient Assistance Program can deliver your medication in 90-day intervals, ensuring you have support if you are uninsured and in need.^f

^fEligibility and restrictions apply. See Terms & Conditions at NovoCare.com

For more personalized assistance and information, visit **NovoCare.com** or call **844-668-6732**
8:00 AM to 8 PM, Monday through Friday EST

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EVERYDAY BLEED PROTECTION^a in a pen designed with you in mind

First prefilled, subcutaneous pen to prevent or reduce frequency of bleeding episodes in adults and children 12 years of age and older with hemophilia B with inhibitors or hemophilia A with inhibitors

^aIt is important to follow the daily dosing schedule of Alhemo® to stay protected against bleeding.

- **Power to prevent bleeds:**

1.7 average and 0 median bleed rate with Alhemo®

- **Portable and ready to use: Prefilled, no mixing required^{b,c}**

Ultra-thin 32G 4 mm needle, low injection volume^d

- **Safe to use** with all bypassing agents (BPAs)^e

- **Safety demonstrated** in 320 patients including 133 with inhibitors

Most common adverse reactions with Alhemo®: Injection site reactions (18%) and urticaria (6%).

320 males with hemophilia A with and without inhibitors and hemophilia B with and without inhibitors received at least 1 dose of Alhemo® as routine prophylaxis. 52 people with inhibitors were previously treated with on-demand therapy and were randomized to receive on-demand treatment with bypassing agents (19 people) or Alhemo® prophylaxis (33 people).

Clinical study of Alhemo® included people ages 12 years and older who had hemophilia B with inhibitors (53 people) and hemophilia A with inhibitors (80 people) who were treated with or are in need of either bypassing agents on demand (at least 24 weeks) or Alhemo® once-daily prophylaxis (at least 32 weeks). 86% annual bleed rate (ABR) reduction with Alhemo® (33 people) compared with on-demand bypassing agents (19 people). The mean ABR was 1.7 for people treated with Alhemo® and 11.8 for people treated with on-demand BPAs. The median ABR was 0 for patients on Alhemo® and 9.8 for patients on no prophylaxis.

^bStore in refrigerator before first use. After first use, Alhemo® can be stored at room temperature below 86 °F (30 °C) or in a refrigerator at 36 °F to 46 °F (2 °C to 8 °C) for up to 4 weeks.

^cRead the Instructions for Use for information about how to prepare and inject Alhemo®, and how to properly throw away used pens and needles. Your healthcare provider should show you or your caregiver how to use Alhemo® before you use it for the first time.

^dFor a person who weighs 70 kg (154 lb) on a daily dose of 0.2 mg/kg and using the (gold label) 150 mg/1.5 mL pen, the volume to inject is 0.14 mL per dose.

^eCarefully follow your healthcare provider's instructions regarding when to use on-demand BPAs and the recommended dose and schedule for breakthrough bleeds.

Important Safety Information (cont'd)

What are the possible side effects of Alhemo®?

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

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NovoFine® is a registered trademark of Novo Nordisk A/S.

Novo Nordisk is a registered trademark of Novo Nordisk A/S.

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Ask your Rare Blood Community Liaison about Alhemo®. Visit [Alhemo.com](https://www.alhemo.com)

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novonordisk