

NOW APPROVED

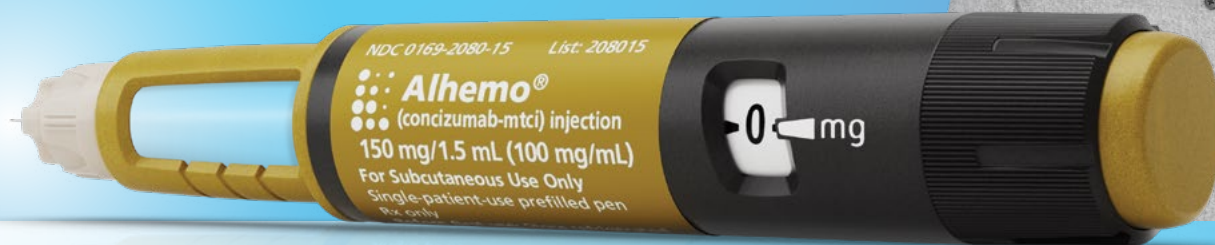
Reimagined bleed protection is now within your reach

First and only prophylaxis treatment in a prefilled, subcutaneous pen for people who have hemophilia B with inhibitors

Alhemo® is a prescription medicine used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children 12 years of age and older with hemophilia A with Factor 8 inhibitors or hemophilia B with Factor 9 inhibitors. It is not known if Alhemo® is safe and effective in people using Alhemo® while receiving ongoing immune tolerance induction. It is not known if Alhemo® is safe and effective for hemophilia A and B with and without inhibitors in children younger than 12 years of age.

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

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



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

Important Safety Information

What is the most important information I need to 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

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

Please see additional Important Safety Information throughout.

Please click [here](#) for Prescribing Information including Medication Guide.

Celebrating
35⁺
YEARS
serving the hemophilia
with inhibitors community



For people living with hemophilia B with inhibitors:

With current treatment options, there are still unexpected bleeds—

let's help change that. >

Bleeds can lead to joint damage, so having preventive treatment is essential.

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

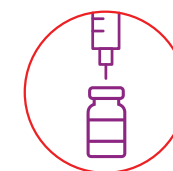
Median Annual Bleed Rate



Bleeds per year when using bypassing agents on demand
n=16^a



Bleeds per year when using bypassing agents as prophylaxis
n=15^a



Current treatments require **IV infusion**, and **involve mixing** and **reconstitution**.

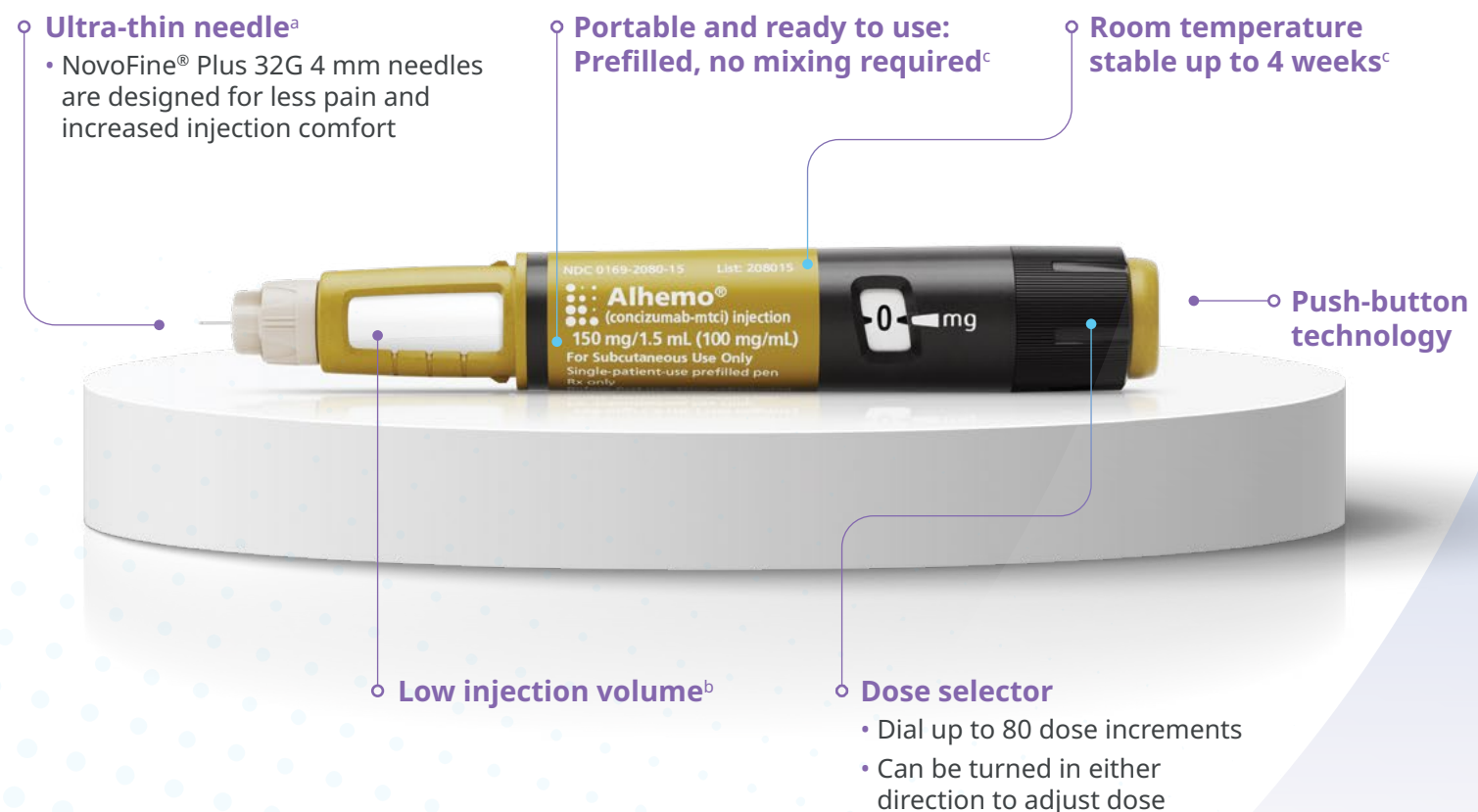
It is time for a treatment **designed with you in mind**—to **prevent bleeds** and **help you manage your condition**.

^aThis 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).

IV=intravenous.

First and only prefilled injection pen for hemophilia B with inhibitors

Subcutaneous administration (no need for vein access)



No IV infusions



No mixing



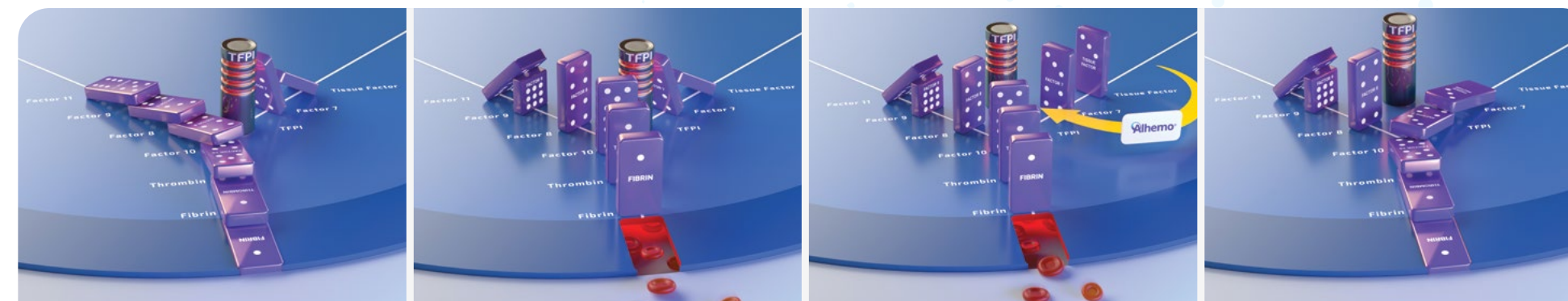
No vials



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

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[®] works even when Factor 9 inhibitors are present

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 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

Please see additional Important Safety Information throughout. Please click [here](#) for Prescribing Information including Medication Guide.



^aNeedles provided separately and may require a prescription in some states; a new needle is required for each injection.
^bFor 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.
^cStore 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.

Alhemo® provided proven effective bleed protection

A study evaluated the safety and efficacy of Alhemo® for routine prophylaxis in 91 adults and in 42 adolescents aged 12 to 17 years who have hemophilia B or A with inhibitors. Participants in the study were treated with either bypassing agents on demand or Alhemo® once-daily prophylaxis over 24 weeks or 32 weeks, respectively. Efficacy was evaluated by comparing the number of treated bleeds between 19 patients who received bypassing agents on demand (no prophylaxis) and 33 patients who received Alhemo® prophylaxis.

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



Primary study results:

1.7 Average annual bleed rate for patients on Alhemo® vs 11.8 for patients on no prophylaxis

86% Reduction in average annual bleed rate compared with no prophylaxis

0 Median annual bleed rate (vs 9.8 on no prophylaxis)

24 bleed-free weeks in more than 6 out of 10 people (vs 1 out of 10 people with no prophylaxis)

Supportive secondary study results

Safety confirmed in explorer7 study



Safety evaluated in 133 people with hemophilia with inhibitors



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. Carefully 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 urticaria, 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.

Important Safety Information (cont'd)

What are the possible side effects of Alhemo®? (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

Please see additional Important Safety Information throughout. Please click [here](#) for Prescribing Information including Medication Guide.

Administering Alhemo[®]—at a glance

- Alhemo[®] is given as an injection under the skin (subcutaneous injection) by you or a caregiver
- Use Alhemo[®] exactly as prescribed by your healthcare provider
- Your healthcare provider should show you or your caregiver how to use Alhemo[®] before you use it for the first time

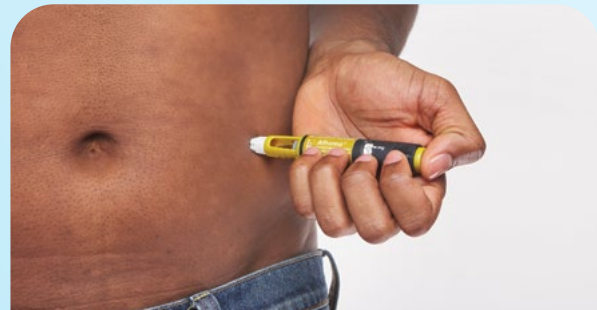
Alhemo[®] is administered once daily.



- 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



- 6 Remove needle
- 7 Recap pen

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

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

Read the Instructions for Use for full instructions on administration:

- Scan QR Code
- Visit Alhemo.com



Alhemo[®] offers dosing individualized to your specific needs

Alhemo[®] requires a test that measures the amount of concizumab-mtci in your blood. This allows your healthcare provider to individualize your Alhemo[®] dose to fit your body's needs.



Day 1:
Start with 1 mg/kg



Day 2 and after:
Dose 0.2 mg/kg daily until dose adjustment



Day 28: (4 weeks after starting Alhemo[®]):
Laboratory developed test^b (at no cost to you)

- Test results take up to 10 working days
- Then **your healthcare provider will adjust your dose, if needed**, by Week 8

To determine the right maintenance dose for you, your healthcare provider will do a laboratory developed test to check the amount of concizumab-mtci in your blood. Your healthcare provider may do additional lab tests during treatment with Alhemo[®].

Follow the daily dosing schedule of Alhemo[®] to stay protected against bleeding. This is especially important during the first 4 weeks, to help establish your maintenance dose.

If you miss a dose during the first 4 weeks, contact your healthcare provider, who will tell you how much to inject.

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

^bShould be performed before administering next scheduled dose.

Important Safety Information (cont'd)

How should I use Alhemo[®]?

- Change (rotate) your injection site with each injection. **Do not** use the same site for each injection
- To determine the right maintenance dose for you, your HCP will do a blood test to check the amount of Alhemo[®] in your blood. Your HCP may do additional blood tests during treatment with Alhemo[®]
- Do not share your Alhemo[®] pens and needles with another person, even if the needle has been changed. You may give another person an infection or get an infection from them
- **If you miss a dose of Alhemo[®] during the first 4 weeks of treatment**, contact your HCP right away. Your HCP will tell you how much Alhemo[®] to inject

Please see additional Important Safety Information throughout.
Please click [here](#) for Prescribing Information including Medication Guide.

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

^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.

You deserve treatment made to fit your lifestyle

Available in 3 pen options to meet your individual dosing needs

Each pen contains multiple doses of Alhemo®



1 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®: Effective bleed protection in an injection pen designed with you in mind

Important Safety Information (cont'd)

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

- Have a planned surgery. Your HCP may stop treatment with Alhemo® before your surgery. Talk to your HCP about when to stop using Alhemo® and when to start it again if you have a planned surgery
- Are pregnant or plan to become pregnant. It is not known if Alhemo® may harm your unborn baby
- **Females who are able to become pregnant**
 - Your HCP may do a pregnancy test before you start treatment with Alhemo®.
 - You should use an effective birth control (contraception) method during treatment with Alhemo® and for 7 weeks after ending treatment. Talk to your HCP about birth control methods that you can use during this time
- Are breastfeeding or plan to breastfeed. It is not known if Alhemo® passes into your breast milk. Talk to your HCP about the best way to feed your baby during treatment with Alhemo®

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

Please see additional Important Safety Information throughout.

Please click [here](#) for Prescribing Information including Medication Guide.

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.^a



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.^a



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.^a

For more personalized assistance and information, please visit [NovoCare.com](#)



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injection | 60 mg | 150 mg | 300 mg pens

^aEligibility and restrictions apply. See Terms & Conditions at [NovoCare.com](#)

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

Reimagined bleed protection is now within your reach

First and only prefilled, subcutaneous pen for **hemophilia B with inhibitors**

Safety evaluated in 133 people with hemophilia with inhibitors

Portable and ready to use: Prefilled, no mixing required^a
• Ultra-thin 32G 4 mm needle, low injection volume^b

Proven effective bleed protection:

- **1.7 Average annual bleed rate** for patients on Alhemo[®] vs 11.8 for patients on no prophylaxis
- **86% Reduction** in average annual bleed rate
- **0 Median annual bleed rate** for patients on Alhemo[®] vs 9.8 on no prophylaxis

Study of the safety and efficacy of Alhemo[®] for routine prophylaxis in 91 adults and in 42 adolescents aged 12 to 17 years who have hemophilia B with inhibitors or hemophilia A with inhibitors. Participants in the study were treated with either bypassing agents on demand or Alhemo[®] once-daily prophylaxis over 24 weeks or 32 weeks, respectively. Efficacy was evaluated by comparing the number of treated bleeds between 19 patients who received bypassing agents on demand (no prophylaxis) and 33 patients who received Alhemo[®] prophylaxis.

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Important Safety Information

What are the possible side effects of Alhemo[®]?

- **The most common side effects of Alhemo[®] include:** bruising, redness, bleeding, or itching at the site of injection, and hives.

Please see additional Important Safety Information throughout. Please click [here](#) for Prescribing Information including Medication Guide.

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

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Ask your Rare Blood Community Liaison about Alhemo[®].

Visit [Alhemo.com](#) or scan QR code.



NDC 0169-2080-15 List: 208015
Alhemo[®]
(concizumab-mtci) injection
150 mg/1.5 mL (100 mg/mL)
For Subcutaneous Use Only
Single-patient-use prefilled pen
Rx only

0
mg

Celebrating
35⁺
YEARS
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novo nordisk[®]