



press release

Health Canada approves REBINYN® (Coagulation Factor IX (Recombinant), pegylated) for the treatment of routine prophylaxis to prevent or reduce frequency of bleeding episodes in children with hemophilia B

Expanded indication for REBINYN® will continue to support Canadian pediatric patients living with hemophilia B

Mississauga, ON, October 26, 2022 – Novo Nordisk announced today that Health Canada has approved a new indication for REBINYN® (Coagulation Factor IX (Recombinant), pegylated) for the treatment of routine prophylaxis in hemophilia B patients that are <18 years of age.¹ REBINYN® is now indicated in all ages with hemophilia B (congenital factor IX deficiency or Christmas disease) for routine prophylaxis to prevent or reduce the frequency of bleeding episodes, control and prevention of bleeding episodes and control and prevention of bleeding in a perioperative setting.²

REBINYN® was previously approved by Health Canada in 2017. In this latest Health Canada approval for routine prophylaxis in <18 years of age, the data reviewed by Health Canada included pediatric previously treated patients (PTPs) on prophylaxis for up to 8-years and pediatric previously untreated patients (PUPs) on prophylaxis for up to 6-years.

In Canada, hemophilia B is a hereditary rare bleeding disorder that affects approximately 1 in 50,000 people, or about 600 Canadians.³ If left untreated, hemophilia can be debilitating and often fatal.⁴

"Novo Nordisk is pleased to expand the REBINYN® indication to ensure Canadians with rare genetic bleeding disorders have innovative treatment options to support their needs," says John Burrows, Vice President, Rare Disease, Novo Nordisk Canada Inc. "We will continue to deliver innovative therapies that play an important role in improving hemophilia care for patients across Canada, and demonstrate our commitment to patients, caregivers, and healthcare professionals. We are committed to making a meaningful difference in the rare disease community."

The completed clinical trial program included one phase 1 trial and four phase 3 multicentre, non-controlled trials. The objectives of the phase 3 trials were to evaluate the safety and efficacy of REBINYN® in routine prophylaxis, control and prevention of bleeding episodes, and perioperative management in pediatric and adult PTPs with hemophilia B (factor IX activity ≤ 2%). One multicenter, non-controlled, open-label trial was conducted to evaluate the safety and efficacy of REBINYN® in routine prophylaxis and treatment of breakthrough bleeding episodes in pediatric PUPs (< 6 years old) with hemophilia B (Factor IX activity ≤ 2%). The efficacy evaluation included 105 PTPs: [62 adults (18 to 65 years old), 18 adolescents (13 to 17 years old), and 25 children (1 to 12 years old)] and 50 PUPs (< 6 years old).⁵

About REBINYN®

Rebinyn® (Coagulation Factor IX [Recombinant], pegylated) is an anti-hemophilic factor indicated in adults and children with hemophilia B (congenital factor IX deficiency or Christmas disease) for:

- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes
- Control and prevention of bleeding episodes
- Control and prevention of bleeding in the perioperative setting

Consult the Product Monograph at

<https://www.novonordisk.ca/content/dam/nncorp/ca/en/products/rebinyn-product-monograph.pdf> for more information on Rebinyn®, including relevant warnings and precautions, adverse reactions, interactions, dosing instructions, and conditions of clinical use. The Product Monograph is also available by calling us at 1-800-465-4334.

About Hemophilia B

Hemophilia B – also known as Christmas Disease or Factor IX deficiency hemophilia, is a hereditary rare bleeding disorder that affects approximately 1 in 50,000 people, or about 600 Canadians.⁶ It is caused by a lack of blood protein called factor IX that slows down the normal clotting process. If left untreated, hemophilia B can lead to serious health complications.⁷

About Novo Nordisk

Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat diabetes and other serious chronic diseases such as obesity and rare blood and endocrine disorders. We do so by pioneering scientific breakthroughs, expanding access to our medicines, and working to prevent and ultimately cure disease. Novo Nordisk employs about 50,800 people in 80 countries and markets its products in around 170 countries. For more information, visit [novonordisk.ca](https://www.novonordisk.ca), or [@NovoNordiskCA](https://twitter.com/NovoNordiskCA) on Twitter.

Further information

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¹ Novo Nordisk Canada Inc. Rebinyn Product Monograph. Available at <https://www.novonordisk.ca/content/dam/nncorp/ca/en/products/rebinyn-product-monograph.pdf>. Accessed September 2022.

² Novo Nordisk Canada Inc. Rebinyn Product Monograph. Available at <https://www.novonordisk.ca/content/dam/nncorp/ca/en/products/rebinyn-product-monograph.pdf>. Accessed September 2022.

³ Canadian Hemophilia Society. What is hemophilia? Available at <https://www.hemophilia.ca/hemophilia-a-and-b/>. Accessed September 2022.

⁴ Novo Nordisk Canada Inc. Rebinyn Product Monograph. Available at <https://www.novonordisk.ca/content/dam/nncorp/ca/en/products/rebinyn-product-monograph.pdf>. Accessed September 2022.

⁵ Novo Nordisk Canada Inc. Rebinyn Product Monograph. Available at <https://www.novonordisk.ca/content/dam/nncorp/ca/en/products/rebinyn-product-monograph.pdf>. Accessed September 2022.

⁶ Canadian Hemophilia Society. What is hemophilia? Available at <https://www.hemophilia.ca/hemophilia-a-and-b/>. Accessed September 2022.

⁷ Novo Nordisk Canada Inc. Rebinyn Product Monograph. Available at <https://www.novonordisk.ca/content/dam/nncorp/ca/en/products/rebinyn-product-monograph.pdf>. Accessed September 2022.