Health Canada approves Rebinyn®, a new, long-acting treatment for patients with hemophilia B in Canada.

April 12nd 2018

To whom it may concern,

Novo Nordisk Canada Inc. is pleased to announce the availability of Rebinyn® (nonacog beta pegol – Recombinant coagulation Factor IX, Pegylated) through Canadian Blood Services. Novo Nordisk received Health Canada approval of Rebinyn® on Nov 29th 2017.

Rebinyn® is a once-weekly, pegylated recombinant factor IX (rFIX) indicated in adults and children with hemophilia B (congenital factor IX deficiency or Christmas disease) for:

- control and prevention of bleeding episodes
- control and prevention of bleeding in the perioperative setting

Rebinyn® is also indicated in patients 18 years and above with hemophilia B for:

- routine prophylaxis to prevent or reduce the frequency of bleeding episodes

Post-Administration Monitoring of Drug Activity Levels

Information has also been included in the product monograph on the use of appropriate assays and reagents for monitoring of drug activity levels. In this context, the following information is included in the WARNINGS AND PRECAUTIONS/ Monitoring and Laboratory Tests section of the Rebinyn® Product Monograph:

Due to the interference of polyethylene glycol (PEG) in the one-stage clotting assay with various aPTT reagents, it is recommended to use a chromogenic assay (e.g. Rox Factor IX or Biophen) when monitoring is needed. If a chromogenic assay is not available, it is recommended to use a one-stage clotting assay with an aPTT reagent (e.g. Cephascreen) qualified for use with Rebinyn® *.For* Rebinyn® *some reagents will cause underestimation (30–50%), while most silica containing reagents will cause severe overestimation of the factor IX activity (more than 400%). Therefore, silica based reagents should be avoided. Use of a reference laboratory is recommended when a chromogenic assay or a qualified one-stage clotting assay is not available locally.*

At this time, the following one-stage clotting assays have been qualified for use with REBINYN®:

- SynthaAFax with ACL platform.
  Note: As long as a lab properly validates their method, any equipment can be used with Synthafax. The advantage of using the ACL top platform is that the machine already has a program for Synthafax and FIX assay installed and this would ease the validation.

- Cephascreen with Stago instrument.

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Note: Cephascreen cannot be used with other machines as it requires mechanical detection which is only installed on the Stago instrument

In consultation with Hemophilia treaters and the AHCDC, Novo Nordisk is supporting a program that provides assistance to coagulation labs that want to complete a validated testing process for Rebinyn® factor levels. To date, there are two designated reference laboratories, St. Michael's Hospital in Toronto and St. Paul's Hospital in Vancouver. Many other centres are in progress. Any coagulation lab that is interested in developing a testing protocol for Rebinyn® may contact their Novo Nordisk Canada Medical Science Liaison or the Medical information team.

For more information, please contact:

- Your Novo Nordisk Canada Medical Science Liaison or
- Novo Nordisk Canada Customer Care and Medical Information department at +1 800 465 4334 or nncicustomercare@novonordisk.com.

Sincerely,

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