Rebinyn® (coagulation factor IX [recombinant] glycoPEGylated) – New drug approval

- On May 31, 2017, Novo Nordisk announced the FDA approval of Rebinyn (coagulation factor IX [recombinant] glycoPEGylated) for use in adults and children with hemophilia B for on-demand treatment and control of bleeding episodes, and perioperative management of bleeding.
    - Rebinyn is not indicated for routine prophylaxis in the treatment of patients with hemophilia B.
    - Rebinyn is not indicated for immune tolerance induction in patients with hemophilia B.
- Hemophilia B is a chronic, inherited bleeding disorder affecting approximately 5,000 Americans. Hemophilia B causes deficient blood clotting factor IX activity, resulting in prolonged and spontaneous bleeding, especially into muscles, joints, or internal organs.
- Rebinyn contains recombinant coagulation factor IX, which temporarily replaces the missing coagulation factor. Rebinyn is conjugated to a 40-kDa polyethylene glycol (PEG) molecule, which slows Rebinyn's removal from blood circulation.
- The safety and efficacy of Rebinyn were based on four non-controlled trials for routine treatment, on-demand treatment and control of bleeding episodes, and perioperative management in previously treated male patients with hemophilia B (factor IX activity ≤ 2%).
    - Good or excellent results were achieved in 93% of patients with bleeding episodes, with most patients only requiring 1 injection.
    - The intraoperative hemostatic effect was rated as excellent or good for the 13 surgeries that were evaluated, for a success rate of 100%.
    - Three additional major surgeries and 18 minor surgery procedures were evaluated in the extension trial for Rebinyn in previously treated patients. The hemostatic effect during major and minor surgery was also confirmed with a success rate of 100%.
- Rebinyn is contraindicated in patients who have known hypersensitivity to Rebinyn or its components, including hamster proteins.
- Warnings and precautions of Rebinyn include hypersensitivity reactions, inhibitors, thrombotic events, nephrotic syndrome, and monitoring laboratory tests.
- The most common adverse events (≥ 1%) with Rebinyn use were itching and injection site reactions.
    - Animals administered repeat doses of Rebinyn showed accumulation of PEG in the choroid plexus. The potential clinical implications of these animal findings are unknown.
- Rebinyn is administered by intravenous infusion. The dose and duration of treatment depend on the location and extent of bleeding, and the patient's clinical condition.
    - The recommended dose for on-demand treatment and control of bleeding episodes is 40 IU/kg body weight for minor or moderate bleeds, and 80 IU/kg body weight for major bleeds. Additional doses of 40 IU/kg can be given.
    - The recommended dose for perioperative management is 40 IU/kg body weight for minor surgery, and 80 IU/kg body weight for major surgery. As clinically needed, repeated doses of 40 IU/kg (in 1 – 3 day intervals) within the first week after major surgery may be administered. Frequency may be extended to once weekly after the first week until bleeding stops and healing is achieved.

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- Consult the drug label for additional dosing information.

- Novo Nordisk plans to launch Rebinyn in the first half of 2018. Rebinyn will be available as a lyophilized powder in single-use vials of 500 IU, 1000 IU, and 2000 IU.