PRODUCT SPECIFICATION SHEET

Rebinyn®, Coagulation Factor IX (Recombinant), GlycoPEGylated

Trade Unit Product Information				
Brand Name	Rebinyn® 500 IU	Rebinyn® 1000 IU	Rebinyn® 2000 IU	Rebinyn® 3000 IU
Generic Name	Coagulation Factor IX (Recombinant), GlycoPEGylated	Coagulation Factor IX (Recombinant), GlycoPEGylated	Coagulation Factor IX (Recombinant), GlycoPEGylated	Coagulation Factor IX (Recombinant), GlycoPEGylated
WAC Price (per IU)	$4.65	$4.65	$4.65	$4.65
Package Presentation	1 carton containing: Rebinyn® in single-dose vial, syringe pre-filled with 4 mL sodium chloride diluent, vial adapter	1 carton containing: Rebinyn® in single-dose vial, syringe pre-filled with 4 mL sodium chloride diluent, vial adapter	1 carton containing: Rebinyn® in single-dose vial, syringe pre-filled with 4 mL sodium chloride diluent, vial adapter	1 carton containing: Rebinyn® in single-dose vial, syringe pre-filled with 4 mL sodium chloride diluent, vial adapter
NDC/List Number	0169-7905-01	0169-7901-01	0169-7902-01	0169-7903-01
UPC	3 01697 90501 3	3 01697 90101 5	3 01697 90201 2	3 01697 90301 9
Bar Code				
Trade Unit Dimensions (inches L × W × H)	4.783 × 2.795 × 1.752	4.783 × 2.795 × 1.752	4.783 × 2.795 × 1.752	4.783 × 2.795 × 1.752
Trade Unit Weight (ounces)	2.399	2.399	2.399	2.399
Storage (Storing Rebinyn® at room temperature [up to 86°F] will reduce expiration date to 6 months.)	• 6 months at room temperature • 24 months refrigerated 36°F-46°F (2°C-8°C) from manufactured date	• 6 months at room temperature • 24 months refrigerated 36°F-46°F (2°C-8°C) from manufactured date	• 6 months at room temperature • 24 months refrigerated 36°F-46°F (2°C-8°C) from manufactured date	• 6 months at room temperature • 24 months refrigerated 36°F-46°F (2°C-8°C) from manufactured date

Important Codes for Rebinyn®

Congenital Factor IX disorder ICD-9: 286.1[1]
ICD-10: D67[2]

Indications and Usage

Rebinyn®, Coagulation Factor IX (Recombinant), GlycoPEGylated, is a recombinant DNA derived coagulation Factor IX concentrate indicated for use in adults and children with hemophilia B (congenital Factor IX deficiency) for on demand treatment and control of bleeding episodes, perioperative management of bleeding, and routine prophylaxis to reduce the frequency of bleeding episodes.

Limitations of Use: Rebinyn® is not indicated for immune tolerance induction in patients with hemophilia B.

Important Safety Information

Contraindications

- Rebinyn® is contraindicated in patients with a known hypersensitivity to Rebinyn® or its components, including hamster proteins.

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Please see additional Important Safety Information on next page.
Please click here for Prescribing Information.

rebinyn®
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PRODUCT SPECIFICATION SHEET

Rebinyn® Administration Kit

Product Name	Rebinyn® Administration Kit (Free of charge. Limited quantities available.)
List Number	720006
NDC/List Number	0169-7200-06
UPC	3 01697 20006 4
Bar Code	3 01697 20006 4
Trade Unit Dimensions (inches L × W × H)	4.125 × 2.625 × 1.5
Trade Unit Weight	0.8 oz
Contents	• 1 winged needle infusion set (25 gauge, DEHP free) • 2 adhesive bandages • 2 gauze pads • 2 alcohol swabs • 1 instructions for use

TO ORDER, CALL: 1-844-REB-INYN (1-844-732-4696)

Important Safety Information (cont'd)

Warnings and Precautions

- **Hypersensitivity Reactions:** Allergic-type hypersensitivity reactions, including anaphylaxis, have occurred with Rebinyn®. Signs may include angioedema, chest tightness, difficulty breathing, wheezing, urticaria, and itching. Discontinue Rebinyn® if allergic- or anaphylactic-type reactions occur and initiate appropriate treatment.
- **Inhibitors:** The formation of inhibitors (neutralizing antibodies) to Factor IX has occurred following Rebinyn®. If expected plasma factor IX activity levels are not attained, or if bleeding is not controlled as expected with the administered dose, perform an assay that measures Factor IX inhibitor concentration. Monitor all patients using clinical observations and laboratory tests for the development of inhibitors. Factor IX activity assay results may vary with the type of activated partial thromboplastin time reagent used.
- **Thrombotic Events:** The use of Factor IX-containing products has been associated with thromboembolic complications. Monitor for thrombotic and consumptive coagulopathy when administering Rebinyn® to patients with liver disease, post-operatively, to newborn infants, or to patients at risk of thrombosis or disseminated intravascular coagulation (DIC).
- **Nephrotic Syndrome:** Nephrotic syndrome has been reported following immune tolerance induction therapy with Factor IX products in hemophilia B patients with Factor IX inhibitors, often with a history of allergic reactions to Factor IX. The safety and efficacy of using Rebinyn® for immune tolerance induction have not been established.

Adverse Reactions

- The most common adverse reactions reported in previously treated patients in clinical trials (≥1%) were itching and injection site reactions. The most common adverse reactions (≥1%) in previously untreated patients reported in clinical trials were rash, FIX inhibitors, hypersensitivity, itching, injection site reaction, and anaphylactic reaction.
- Animals administered Rebinyn® showed accumulation of PEG in the choroid plexus, pituitary, circumventricular organs, and cranial motor neurons. The potential clinical implications of these animal findings are unknown. Consider whether the patient is vulnerable to cognitive impairment, such as infants and children who have developing brains, and patients who are cognitively impaired.

References: 1. Centers for Disease Control and Prevention. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM). Updated June 18, 2013. Accessed September 6, 2022. ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD9-CM/2011/ **2.** Centers for Disease Control and Prevention. International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM). Updated October 1, 2019. Accessed September 6, 2022. https://icd10cmtool.cdc.gov/?fy=FY2022&query=hemophilia%20b

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