

Product Specifics	ALPROLIX® Bioverativ	BeneFIX® Pfizer	IDELVION® CSL Behring	IXINITY® Aptevo	Rebiny® Novo Nordisk	RIXUBIS® Shire										
Indications	ALPROLIX [Coagulation Factor IX (Recombinant), Fc Fusion Protein] is a recombinant DNA derived, coagulation factor IX concentrate indicated in adults and children with Hemophilia B for: <ul style="list-style-type: none"> On-demand treatment and control of bleeding episodes Perioperative management of bleeding Routine prophylaxis to reduce the frequency of bleeding episodes. ALPROLIX is not indicated for induction of immune tolerance in patients with Hemophilia B.	BeneFIX, Coagulation Factor IX (Recombinant), is indicated for the control and prevention of hemorrhagic episodes in adult and pediatric patients with hemophilia B (congenital factor IX deficiency or Christmas disease), including management of hemostasis in surgical settings.	Children and adults with hemophilia B (congenital Factor IX deficiency) for: <ul style="list-style-type: none"> On-demand control and prevention of bleeding episodes Perioperative management of bleeding Routine prophylaxis to prevent or reduce the frequency of bleeding episodes IDELVION is not indicated for immune tolerance induction in patients with hemophilia B.	Adults and children at least 12 years of age with hemophilia B for control and prevention of bleeding episodes, and for perioperative management	Adults and children with hemophilia B for: <ul style="list-style-type: none"> On-demand treatment and control of bleeding episodes Perioperative management of bleeding Limitations of Use: Rebiny® is not indicated for routine prophylaxis in the treatment of patients with hemophilia B. Rebiny® is not indicated for immune tolerance induction in patients with hemophilia B	Indicated in adults and children with hemophilia B for: Control and prevention of bleeding episodes, perioperative management, and routine prophylaxis. RIXUBIS is not indicated for induction of immune tolerance in patients with hemophilia B.										
Contraindications	Do not use in individuals who have a known history of hypersensitivity reactions, including anaphylaxis, to the product or its excipients.	Because BeneFIX, Coagulation Factor IX (Recombinant), is produced in a Chinese hamster ovary cell line, it may be contraindicated in patients with a known history of hypersensitivity to hamster protein. BeneFIX is contraindicated in patients who have manifested life-threatening, immediate hypersensitivity reactions, including anaphylaxis, to the product or its components.	Do not use in patients who have had life-threatening hypersensitivity reactions to IDELVION or its components, including hamster proteins.	Hypersensitivity to IXINITY or its excipients, including hamster protein	Do not use in patients who have known hypersensitivity to Rebiny® or its components, including hamster proteins	Do not use in patients with: Known hypersensitivity to RIXUBIS or its excipients including hamster protein. Disseminated intravascular coagulation. Signs of fibrinolysis										
Viral Safety Processes	To enhance viral safety, the purification process incorporates a nanofiltration step and a column chromatography purification step that have been validated for viral clearance. The content of activated Factor IX Fc fusion protein (FIXaFc) is limited to ≤0.035 mole percent FIXaFc/FIXFc.	Purified by a chromatography purification process that does not require a monoclonal antibody step and yields a high-purity, active product. The process also includes a membrane nanofiltration step that has the ability to retain molecules with apparent molecular weights >70,000 (such as large proteins and viral particles).	The manufacturing process incorporates three validated virus clearance steps, including virus inactivation by solvent/detergent treatment and virus removal by filtration.	Purified by a chromatography purification process that includes three validated steps for virus inactivation and removal - solvent/detergent treatment, a chromatographic step, and nanofiltration. The manufacturing process also includes a validated step to reduce the presence of CHO proteins in the final drug product.	The production process includes two dedicated viral clearance steps: <ul style="list-style-type: none"> A detergent treatment step for inactivation A 20 nm filtration step for removal of viruses 	15 nm Nanofiltration. Solvent/Detergent Treatment.										
Product Half Life	<table border="0"> <tr> <td>50 IU/kg</td> <td>100 IU/kg</td> </tr> <tr> <td>Adults: 86 (37%)</td> <td>97 (35%)</td> </tr> <tr> <td>12 to 17 years: 80 (15%)</td> <td>94 (24%)</td> </tr> <tr> <td>6 to <12 years: 72 (23%)</td> <td></td> </tr> <tr> <td><6 years: 68 (24%)</td> <td></td> </tr> </table>	50 IU/kg	100 IU/kg	Adults: 86 (37%)	97 (35%)	12 to 17 years: 80 (15%)	94 (24%)	6 to <12 years: 72 (23%)		<6 years: 68 (24%)		Adults and Adolescents (>15 years): 18.8 ± 5.4h Adolescents (≥12 years to ≤15 years): 21.1 ± 4.5h Children (≥2 years to <12 years): 19.8 ± 4.0h	0 to <6 years: 90 (CV 13%) hours 6 to <12 years: 93 (CV 21%) hours 12 to <18 years: 87 (CV 36%) hours ≥18 years: 104 (CV 25%) hours (50 IU/kg dose)	Terminal Half-life (hours) 24 (± 7)	0-6 years: 69.6 hours 7-12 years: 76.3 hours 13-17 years: 89.4 hours > 18 years: 83.0 hours	Mean 1/2 life after 1st dose 26.7
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Storage Requirements	Store ALPROLIX™ in the original package in order to protect it from light. Store ALPROLIX™ at 2°C to 8°C (36°F to 46°F). ALPROLIX™ may also be stored at room temperature, not to exceed 30°C (86°F) for a single 6 month period. On the carton, record the date when the product was removed from refrigeration. Use the product before the end of this 6 month period or discard it. Do not place the product back into refrigeration after warming to room temperature. Do not freeze. Freezing will damage the pre-filled diluent syringe. Do not use product or diluent after the expiration date printed on the carton, vial or syringe. Reconstituted product may be stored at room temperature, not to exceed 30°C (86°F) for no longer than 3 hours. Protect from direct sunlight. Discard any product not used within 3 hours after reconstitution.	For products labeled for Room Temperature Storage, store at 2-30°C (not to exceed 30°C). Room Temperature labeled BeneFIX may also be stored under refrigeration (2 to 8°C or 36 to 46°F). For products labeled for Refrigerated Storage, store at 2-8°C, prior to expiration date. Refrigerated Storage labeled BeneFIX may also be stored at room temperature not to exceed 30°C (86°F) for up to 6 months. Freezing should be avoided to prevent damage to the diluent syringe. Do not use BeneFIX after the expiry date on the label. If the product kit labeled for refrigerated storage has been removed from refrigeration and stored at room temperature (not to exceed 30°C or 86°F), the expiration period should be up to 6 months from the date of removal from refrigeration. Do not use the product once this six month period has elapsed even if the expiration date on the carton has not been exceeded. **Refrigerated product is no longer being manufactured or distributed by Pfizer Inc. The last expiration date of the last lot packaged for the US is 3/31/2014.	<ul style="list-style-type: none"> Store IDELVION in its package to protect from light. Store the IDELVION package in the refrigerator or at room temperature 2-25°C (36 to 77°F). Do not freeze. Do not use IDELVION or the Sterilized Water for Injection diluent beyond the expiration date printed on the carton and vial labels. 	Store product at 2 to 25 degrees C (36 to 77 degrees F). Do not freeze. Infuse reconstituted solution immediately or within 3 hours of storage at room temperature. Do not refrigerate after reconstitution.	<ul style="list-style-type: none"> Store Rebiny® in the original package in order to protect from light. Store Rebiny® under refrigeration at a temperature of 36°F-46°F (2°C – 8°C) for up to 24 months from the date of manufacture until the expiration date stated on the label. Rebiny® may be stored at room temperature not to exceed 86°F (30°C) for up to 6 months within the 24-month time period. Record the date when the product was removed from the refrigerator in the space provided on the outer carton. The total time of storage at room temperature should not exceed 6 months. Do not return the product to the refrigerator. Do not use Rebiny® after the end of the 6-month period at room temperature storage, or after the expiration date stated on the vial, whichever occurs earlier. Do not freeze Rebiny®. Use Rebiny® within 4 hours after reconstitution when stored at room temperature. Store the reconstituted product in the vial. Discard any unused reconstituted product stored at room temperature for more than 4 hours. 	Store at refrigerated temperature [2°C to 8°C (36°C to 46°F)] or room temperature [not to exceed 30°C (86°F)] for up to 36 months. Do not freeze.										
Shelf Life from Date of Manufacture	36 months from the date of manufacture	For products labeled for Room Temperature Storage, the shelf life is 24 months when stored at 2-30°C (not to exceed 30°C). For products labeled for Refrigerated Storage, the shelf-life is 36 months when stored at 2-8°C; if stored at room temperature (2-30°C; not to exceed 30°C) prior to the expiration date, then the shelf life becomes 6 months. **Refrigerated product is no longer being manufactured or distributed by Pfizer Inc. The last expiration date of the last lot packaged for the US is 3/31/2014.	36 months	24 months	Under refrigeration: Up to 24 months from the date of manufacture until the expiration date as stated on the label Rebiny® may be stored at room temperature not to exceed 86°F (30°C) for up to 6 months within the 24-month time period. Record the date when the product was removed from the refrigerator in the space provided on the outer carton. The total time of storage at room temperature should not exceed 6 months. Do not return the product to the refrigerator or use after the end of the 6-month period.	36 months										
How Supplied / Diluent Volume	250, 500, 1000, 2000, 3000 & 4000 IU - all sizes in 5mL	5 mL (nominally 250, 500, 1000, 2000, or 3000 IU vials)	2.5mL (250, 500 or 1000 IU vials) or 5mL (2000 IU vials)	5 mL of SWI supplied with each packaged kit	4mL (500 IU, 1000 IU, 2000 IU) The diluent for reconstitution of Rebiny® is histidine and is supplied as a clear colorless solution in a pre-filled diluent syringe.	5 mL										