

Product Specifics	IXINITY® Aptevo	IDELVION® CSL Behring	ALPROLIX™ Biogen	RIXUBIS Shire	BeneFIX® Pfizer
Indications	Adults and children at least 12 years of age with hemophilia B for control and prevention of bleeding episodes, and for perioperative management	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 	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.	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.	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.
Contraindications	Hypersensitivity to IXINITY or its excipients, including hamster protein	Do not use in patients who have had life-threatening hypersensitivity reactions to IDELVION or its components, including hamster proteins.	ALPROLIX™ is not indicated for induction of immune tolerance in patients with Hemophilia B.	Do not use in patients with: Known hypersensitivity to RIXUBIS or its excipients including hamster protein. Disseminated intravascular coagulation. Signs of fibrinolysis	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.
Viral Safety Processes	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 incorporates three validated virus clearance steps, including virus inactivation by solvent/detergent treatment and virus removal by filtration.	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.	15 nm Nanofiltration. Solvent/Detergent Treatment.	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).
Product Half Life	Terminal Half-life (hours) 24 (± 7)	0 to <6 years: 13 hours 6 to <12 years: 21 hours 12 to <18 years: 36 hours	86.52 hours in adults 83.59 hours in adolescents 12-17 years	Mean 1/2 life after 1st dose 26.7	18.8 ± 5.4 hours.
Product Recovery Percentage	Mean recovery, 0.98 IU/dL per IU/kg	Incremental recovery recorded 30 minutes after injection: 0 to <6 years: .95 IU/dL per IU/kg 6 to <12 years: 1.06 IU/dL per IU/kg 12 to <18 years: 1.11 IU/dL per IU/kg	1.0154 IU/dL per IU/kg in adults 0.8929 IU/dL per IU/kg in adolescents 12-17 years	Mean incremental recovery in ((IU/dL)/(IU/kg)) 0.67 (± 0.16)	0.8 ± 0.2 IU/dL per IU/kg infused (Mean increase in adults from pre-infusion level)
Manufacturing Method	Third generation recombinant factor IX	A purified protein produced by recombinant DNA technology	ALPROLIX™ is a recombinant factor IX.	Purified protein produced by recombinant DNA technology	A purified protein produced by recombinant DNA technology
Storage Requirements	Store product at 2 to 25 degrees C (36 to 77 degrees F). 250 IU strength only; store at 2 to 8 degrees C (36 to 46 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 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 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.	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.	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.
Shelf Life from Date of Manufacture	24 months	250 and 500 IU sizes: 24 months 1000 and 2000 IU sizes: 36 months	36 months from the date of manufacture	36 months	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.
How Supplied / Diluent Volume	5 mL of SWI supplied with each packaged kit	2.5mL (250, 500 or 1000 IU vials) or 5mL (2000 IU vials)	5mL = 500 IU, 1,000 IU, 2,000 IU & 3,000 IU	5 mL	5 mL