

# Coagulation Factor IX



800.948.9834 ■ www.bdipharma.com

PRODUCT SPECIFICS	AlphaNine® SD	BeneFIX®	Profilnine® SD	Mononine®	Bebulin VH
INDICATIONS	Factor IX deficiency due to Hemophilia B	BeneFIX®, Coagulation Factor IX (Recombinant), is indicated for the control and prevention of bleeding episodes in adult and pediatric patients with hemophilia B (congenital factor IX deficiency or Christmas disease). BeneFIX®, Coagulation Factor IX (Recombinant), is indicated for peri-operative management in adult and pediatric patients with hemophilia B. BeneFIX®, Coagulation Factor IX (Recombinant), is NOT indicated for: (1) treatment of other factor deficiencies (e.g., factors II, VII, VIII, and X), (2) treatment of hemophilia A patients with inhibitors to factor VIII, (3) reversal of coumarin-induced anticoagulation, (4) treatment of bleeding due to low levels of liver-dependent coagulation factors.	Factor IX deficiency due to Hemophilia B	Prevention and control of bleeding in Factor IX deficiency, also known as Hemophilia B or Christmas disease.	For prevention and control of hemorrhagic episodes in patients with Hemophilia B. See PI for additional detail.
CONTRAINDICATIONS	None Known	BeneFIX® is contraindicated in patients who have manifested life-threatening, immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including hamster protein.	None Known	Known hypersensitivity to mouse protein	None known
VIRAL REMOVAL PROCESS	DEAE Chromatography, Dual Affinity Chromatography and Nanofiltration	Purified by a chromatography purification process that does not require a monoclonal antibody step and yields a high-purity, active product. A membrane filtration step that has the ability to retain molecules with apparent molecular weights >70,000 (such as large proteins and viral particles) is included for additional viral safety.	DEAE Chromatography	Monoclonal antibody immunoaffinity chromatography and two sequential ultrafiltration steps	Ion exchange adsorption
VIRAL INACTIVATION PROCESS	Solvent/Detergent Treatment with a mixture of Tri (n-butyl) phosphate (TNBP) and Polysorbate 80	BeneFIX® is a recombinant FIX product that is not derived from human blood and its manufacturing and purification process include no added human or animal proteins.	Solvent/Detergent Treatment with a mixture of Tri (n-butyl) phosphate (TNBP) and Polysorbate 80	Sodium Thiocyanate	2 step vapor heating, 10 hours at 60°C followed by 1 hour at 80°C at 375 mbar
PRODUCT HALF LIFE	21 hours	18.1 ± 5.1 hrs	24.68 ± 8.29 hours	22.6 to 25.3 hours	19.4 ± 3.8, 24/6 ± 3/2, 19.97 ± 8.24 hours
PRODUCT RECOVERY PERCENTAGE	Approximately 48%	38.7% ± 14.0 (adult)	1.15 ± 0.16 IU/dl per IU infused per kg body weight	1% per IU/kg	53.3 ± 9.6, 57/7 ± 21.8, 53.24 ± 16.95%
MANUFACTURING METHOD	Plasma derived	A purified protein produced by recombinant DNA technology	Plasma derived	Pooled human plasma	Plasma
STORAGE REQUIREMENTS	2°-8°C, do not freeze diluent. Stable at room temperature not to exceed 30°C for up to 1 month	Product as packaged for sale: BeneFIX®, Coagulation Factor IX (Recombinant), can be stored at room temperature or under refrigeration, at a temperature of 2 to 30°C (36 to 86°F). Do not use BeneFIX® after the expiration date on the label. Do not freeze to prevent damage to the diluent syringe. Product after reconstitution: The product does not contain a preservative and should be used within 3 hours.	Store at or below 25°C (77°F). Do not freeze.	Store in refrigerator, 2-8°C (36-46°F) for the period indicated by the expiration date on the label. Within this period, Mononine® may be stored at room temperature not to exceed 25°C (77°F), for up to one month. Avoid freezing, which may damage container for the diluent.	2-8°C
SHELF LIFE FROM DATE OF MANUFACTURE	3 years, up to the date printed on the label, when stored at 2°-8°C.	24 months	Stable for three years, up to the expiration date printed on its label, provided that the storage temperature does not exceed 25°C (77°F).	24 months	24 months
DILUENT VOLUME	10mL = 500 IU, 1000 IU, 1500 IU	5 mL	500 IU = 5mL; 1000 & 1500 IU = 10mL	500 IU - 5 mL, 1000 IU - 10 mL	20 mL

IMPORTANT NOTICE - The information provided herein is a summary of available information only. This summary is to be used as a general educational tool and is not intended for use as a guideline for clinical evaluations. Such evaluations (including but not limited to initial and/or subsequent dosing, conversions from specific product brands, etc.) should utilize a thorough review of appropriate clinical data. For a copy of a product insert or to request any additional information at our disposal, please contact us at 1-800-948-9834. The possibility of error (typographical or otherwise) exists in this summary. No liability is assumed by the distributor for improper use of this literature. ©2011. BDI Pharma, Inc. All rights reserved.