Plasma-Derived Factor IX

Product Specifics	AlphaNine® SD Grifols	Bebulin Shire	Mononine® CSL Behring	Profilnine® Grifols
Indications	AlphaNine SD is indicated for the prevention and control of bleeding in patients with Factor IX deficiency due to hemophilia B. AlphaNine SD contains low, non-therapeutic levels of Factors II, VII, and X, and, therefore, is not indicated for the treatment of Factor II, VII or X deficiencies. This product is also not indicated for the reversal of coumarin anticoagulant-induced hemorrhage, nor in the treatment of hemophilia A patients with inhibitors to Factor VIII.	BEBULIN is indicated for the prevention and control of bleeding episodes in adult patients with hemophilia B (congenital Factor IX deficiency or Christmas disease) BEBULIN is not indicated for use in the treatment of Factor VII deficiency. No clinical studies have been conducted to show benefit from this product for treating deficiencies other than Factor IX deficiency.	Prevention and control of bleeding in Factor IX deficiency, also known as Hemophilia B or Christmas disease.	(factor IX complex) indicated for the prevention and control of bleeding in patients with factor IX deficiency (hemophilia B). Profilnine contains non-therapeutic levels of factor VII and is not indicated for use in the treatment of factor VII deficiency.
Contraindications	None Known	BEBULIN is contraindicated in patients with: Known history of hypersensitivity reactions to the product Known allergy to heparin Known history of heparin-induced thrombocytopenia	Known hypersensitivity to mouse protein	None Known
Viral Safety Processes	DEAE Chromatography, Dual Affinity Chromatography and Nanofiltration. Solvent/Detergent Treatment with a mixture of Tri (n-butyl) phosphate (TNBP) and Polysorbate 80.	35 nm nanofiltration, DEAE-Sephadex adsorption. Vapor heat treatment process [10 hours at 60 °C and subsequent 1 hour at 80 °C under the condition of 7-8% (w/v) residual moisture].	Monoclonal antibody immunoaffinity chromatography and nanofiltration	DEAE Chromatography and nanofiltration. Solvent/Detergent Treatment with a mixture of Tri (n-butyl)phosphate (TNBP) and Polysorbate 80.
Product Half Life	21 hours	19.4 ± 3.8, 24.6 ± 3.2, 19.97 ± 8.24 hours	22.6 - 25.3 hours	24.68 ± 8.29 hours
Product Recovery Percentage	Approximately 48%	53.3 ± 9.6, 57.7 ± 21.8, 53.24 ± 16.95%	0.67-0.68 IU/dL/IU/kg	1.15 ± 0.16 IU/dL per IU infused per kg body weight
Manufacturing Method	Plasma derived	Plasma	Pooled human plasma	Plasma derived
Storage Requirements	2°-8°C (36°-46°F), do not freeze diluent. Stable at room temperature not to exceed 30°C for up to 1 month.	Store at refrigerated temperature (2°C-8°C, 35°F-46°F). Do not use BEBULIN past the expiration date printed on the unit carton. Do not freeze.	When stored at refrigerator temperature, 2-8°C (36-46°F), Mononine® is stable for the period indicated by the expiration date on its 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.	Store at or below 25°C (77°F). Do not freeze.
Shelf Life from Date of Manufacture	3 years, up to the date printed on the label, when stored at 2°-8°C.	24 months	24 months	Stable for three years at room temperature, up to the expiration date printed on its label, provided that the storage temperature does not exceed 25°C (77°F).
How Supplied / Diluent Volume	10 mL for 500 IU, 1000 IU, 1500 IU	20 mL	500 IU - 5 mL, 1,000 IU - 10 mL	5 mL for 500 IU 10 mL for 1000 & 1500 IU