

Product Specifics	AlphaNine® SD Grifols	Profilnine® Grifols	Mononine® CSL Behring	Bebulin Shire
Indications	Factor IX deficiency due to Hemophilia B	(factor IX complex) indicated for the prevention and control of bleeding in patients with factor IX deficiency (hemophilia B)	Prevention and control of bleeding in Factor IX deficiency, also known as Hemophilia B or Christmas disease.	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.
Contraindications	None Known	None Known	Known hypersensitivity to mouse protein	BEBULIN is contraindicated in patients with: Known history of hypersensitivity reactions to the product Known allergy to heparin Known history of heparin-induced thrombocytopenia
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.	DEAE Chromatography and nanofiltration. Solvent/Detergent Treatment with a mixture of Tri (n-butyl)phosphate (TNBP) and Polysorbate 80.	Monoclonal antibody immunoaffinity chromatography and two sequential ultrafiltration steps. Sodium Thiocyanate.	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].
Product Half Life	21 hours	24.68 ± 8.29 hours	22.6 - 25.3 hours	19.4 ± 3.8, 24.6 ± 3.2, 19.97 ± 8.24 hours
Product Recovery Percentage	Approximately 48%	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	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.	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.	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.
Shelf Life from Date of Manufacture	3 years, up to the date printed on the label, when stored at 2°-8°C.	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).	24 months	24 months
How Supplied / Diluent Volume	10 mL for 500 IU, 1000 IU, 1500 IU	5 mL for 500 IU 10 mL for 1000 & 1500 IU	500 IU - 5 mL, 1,000 IU - 10 mL	20 mL