BDIPharma℠

Coagulation Factor IX

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Product Specifics	AlphaNine® SD	ProfiInine® SD	Mononine®	BeneFIX®	Bebulin VH
Indications	Factor IX deficiency due to Hemophilia B	Factor IX deficiency due to Hemophilia B	Prevention and control of bleeding in Factor IX deficiency, also known as Hemophilia B or Christmas disease.	BeneFIX®, Coagulation Factor IX (Recombinant), is indicated for the control and prevention of hemorrhagic episodes in patients with hemophilia B (congenital factor IX deficiency or Christmas disease), including control and prevention of bleeding in surgical settings.	For prevention and control of hemorrhagic episodes in patients with Hemophilia B
Contraindications	None Known	None Known	Known hypersensitivity to mouse protein	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.	None Known
Viral Removal Process	DEAE Chromatography, Dual Affinity Chromatography and Nanofiltration	DEAE Chromatography	Monoclonal antibody Immuno-Affinity chromatography and two sequential ultrafiltration steps	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.	N/A
Viral Inactivation Process	Solvent/Detergent Treatment with a mixture of Tri (n-butyl) phosphate (TNBP) and Polysorbate 80	Solvent/Detergent Treatment with a mixture of Tri (n-butyl) phosphate (TNBP) and Polysorbate 80	Sodium Thiocyanate	None. BeneFIX® is inherently free from the risk of transmission of human blood-borne pathogens such as HIV, hepatitis viruses, and parvovirus.	2 step vapor heating, 60˚ C x 10 hours, 80˚ C at 1 hour
Product Half Life	21 hours	24.68 ± 8.29 hours	22.6 to 25.3 hours	18.8 ± 5.4 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	0.8 + 0.2 iu/dL per iu/kg infused (Mean increase from pre-infusion level)	53.3 ± 9.6, 57.7 ± 21.8, 53.24 ±16.95 %
Manufacturing Method	Plasma Derived	Plasma Derived	Plasma Derived	A purified protein produced by recombinant DNA technology	Plasma
Storage Requirements	2˚-8˚C, do not freeze diluent. Stable at room temperature not to exceed 30˚C for up to 1 month	2˚-8˚C. Do not freeze diluent. Stable at room temperature not to exceed 30˚C for up to 3 months.	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.	Refrigeration at a temperature of 2˚-8˚C (36˚-46˚F). Prior to the expiration date, BeneFIX® may also be stored at room temperature not to exceed 25˚C (77˚F) for up to 6 months. Freezing should be avoided to prevent damage to the diluent syringe. Do not use BeneFIX® after the expiration date on the label.	2˚-8˚C
Shelf Life from Date of Manufacture	2 years	2 years	24 months	36 months	24 months
Diluent Volume	10 mL = 500 iu, 1000 iu, 1500 iu	500 iu = 5 mL 1000 &1500 iu = 10 mL	500 iu - 5 mL, 1000 iu - 10 mL	5 mL for all vial sizes	20 mL