

Comparison Chart of Hemophilic Factor VII, IX and Anti-Inhibitor Complex

Product Specifics	Novoseven®	Febia VH	Mononine®	AlphaNine® SD	Bebulin VH	Profilnine® SD
Indications	Treatment of bleeding episodes in hemophilia A or B patients with inhibitors to Factor VIII or Factor IX	Hemophilia A & B patients with inhibitors and patients with acquired inhibitors to FVIII, FIX, and FXII	Hemophilia B	Factor IX deficiency due to Hemophilia B	Hemophilia B	Factor IX deficiency due to Hemophilia B
Contraindications	Hypersensitivity to Novoseven or any of the components of NovoSeven. Hypersensitivity to mouse, hamster, or bovine protein	Patients who are known to have a normal coagulation mechanism	Hypersensitivity to mouse protein	None Known	None Known	None Known
Viral Removal Process	Chromatographic Purification Process to remove exogenous viruses	N/A	Monoclonal Antibody Immunoaffinity Chromatography and Ultrafiltration	DEAE Chromatography/ Dual Affinity Chromatography/Nanofiltration	N/A	DEAE Chromatography
Viral Inactivation Process	N/A	Vapor Heat Treatment 60°C 10 hrs, 190mbar., then 80°C 1 hour, 370mbar.	Sodium Thiocyanate	Solvent/Detergent Treatment with a mixture of Tri (n-butyl) phosphate (TNBP) and Polysorbate 80	Vapor Heat Treatment 60°C 10 hrs, 190mbar., then 80°C 1 hour, 375mbar.	Solvent/Detergent Treatment with a mixture of Tri (n-butyl) phosphate (TNBP) and Polysorbate 80
Degree of Purity	pH of approximately 5.5 in Sodium Chloride (3mg/ml), Calcium Chloride Dihydrate (1.5mg/ml), Glycylglycine (1.3mg/ml), Polysorbate 80 (0.1mg/ml), and Mannitol (30mg/ml)	N/A	Ultra-High	210iu/mg	N/A	4iu/mg
Product Half-Life	The median residence time was 3.0 hrs. (range 2.4-3.3) and the T 1/2 was 2.3 hrs. (range 1.7-2.7)	N/A	22.6 hours	21 hours	19.91 ± 8.24 hours	24.68 ± 8.29 hours
Product Recovery Percentage	Median in vivo plasma recovery was 44% (30-71%)	N/A	1% per iu/kg	approximately 48%	56.24 ± 16.95%	1.15 ± 1.16 iu/dl per iu infused per kg body weight
Source Plasma	N/A	Paid Donor Pool	Paid Donor Pool	Paid Donor Pool	Paid Donor Pool	Paid Donor Pool
Storage Requirements	Refrigeration 2°-8°C or 36°-46°F Avoid exposure to direct sunlight	Refrigeration 2°-8°C (36°-46°F). May be stored at room temperature not to exceed 25°C (77°F) for up to 6 months or until expiration date, whichever comes first.	Refrigeration or 1 month at room temperature	2°-8°C do not freeze diluent or room temperature not to exceed 30°C for up to 1 month	Refrigeration 2°-8°C (36°-46°F)	2°-8°C do not freeze diluent or room temperature not to exceed 30°C for up to 3 months
Shelf Life	30 months, check label for specific dates	24 months	2 years	2 years from date of manufacture	24 months	2 years from date of manufacture
Diluent Volume	1.2mg vial + 2.2ml 2.4mg vial + 4.3ml 4.8mg vial + 8.5ml Sterile water for Injection, USP	20ml	5ml or 10ml	10ml	20ml	500iu = 5ml 1000&1500iu = 10ml