

FACTOR IX CONCENTRATES HIGH PURITY (RECOMBINANT AND HUMAN)

	BENEFIX	MONONINE	ALPHANINE-SD
<i>MANUFACTURER</i>	Wyeth	CSL Behring	Grifols
<i>CATEGORY</i>	RECOMBINANT	HUMAN, HIGH PURITY	HUMAN, HIGH PURITY
<i>CELL LINE FORMULATION, SOURCE MATERIAL</i>	Chinese hamster ovary (CHO) cells	Pooled human plasma, albumin added as stabilizer	Pooled human plasma, albumin added as stabilizer
<i>PROTEIN PURIFICATION & VIRAL ATTENUATION METHODS</i>	four chromatography steps	monoclonal antibody immunoaffinity chromatography	ion exchange chromatography
	membrane-based filtration	viral-retentive ultrafiltration	dual affinity chromatography
		final chromatography	solvent/detergent
<i>ALBUMIN USE IN MANUFACTURING PROCESS</i>	NONE	n/a	n/a
<i>SPECIFIC ACTIVITY (amount of clotting activity per weight of substance)</i>	Range of 265-286 units/mg of protein (+/- 23 units), final product	188 +/- 14 units/mg of protein, final product	205 units/mg of protein, final product
<i>MEAN HALF LIFE</i>	19.4 +/- 5.4 hours	22-25 hours	21 hours
<i>BOX CONTENTS</i>	Diluent: 5ml prefilled syringe; vial adapter; 23g infusion set; alcohol swabs; bandaid, gauze pad	Diluent: Sterile Water 5ml, 1000 high = 10ml; transfer needle; filter spike; alcohol swabs; 25g winged infusion	Diluent: 10ml Sterile Water (all assays); transfer needle; filter needle
<i>STORAGE REQUIREMENTS</i>	Refrigerate or store at room temperature for up 6 months	Refrigerate or store at room temperature for up to 1 month	Refrigerate
<i>COMMENTS</i>	REQUIRES INCREASED DOSE BY 20% FROM STANDARD FACTOR IX DOSING FORMULA. PEDIATRIC PATIENTS REQUIRE RECOVERY STUDIES AND POTENTIALLY HIGHER DOSES.		
	Recombinant technology may be ONLY product of choice for patients of Jehovah Witness faith.		