

## FACTOR VIII CONCENTRATES--RECOMBINANT

	RECOMBINATE	KOGENATE-FS	HELIXATE-FS	REFACTO	ADVATE	XYNTHA
<i>Manufacturer</i>	BAXTER	BAYER	BAYER, distributed by CSL BEHRING	WYETH	BAXTER	WYETH
<i>Generation of Product</i>	first <sup>(1)</sup>	second <sup>(2)</sup>		second <sup>(2)</sup>	third <sup>(3)</sup>	third <sup>(3)</sup>
<i>Cell line</i>	Chinese Hamster Ovary (CHO) cells	Baby Hamster kidney (BHK) cells		Chinese Hamster Ovary (CHO) cells; non-essential B-domain deleted,	Chinese Hamster Ovary (CHO) cells	Chinese Hamster Ovary (CHO) cells
<i>Protein Purification Methods</i>	monoclonal antibody immunoaffinity chromatography	anion exchange chromatography; gel filtration; monoclonal antibody immunoaffinity chromatography		five chromatography steps	monoclonal antibody immunoaffinity chromatography	Chromatography series: affinity chromatography
<i>Viral Attenuation Methods</i>	no specific method <sup>(4)</sup>	solvent detergent		solvent detergent	solvent detergent	Solvent detergent; virus-retaining nanofiltration
<i>Albumin used in manufacturing process</i>	yes (human)	yes (human)		yes (human)	no	no
<i>Albumin used as a stabilizer</i>	yes (bovine)	no (stabilized with sucrose)		no (stabilized with sucrose)	no	no
<i>Mean Half Life of Factor</i>	14.4 +/- 4.9 hours	13 hours		14.5 +/- 5.3 hours	11.98 +/- 4.28 hours	11.2 +/- 5.0 (initial) 11.8 +/- 6.2 (6-month)
<i>Box Contents</i>	Diluent: 10 ml (all sizes) Sterile Water; Baxject Mixing Device	Diluent: 2.5 ml (all sizes) Sterile Water; transfer needle, filter needle; 25g infusion set Bioset Mixing Device: 2.5ml Sterile Water pre-filled syringe; 25g infusion set	Diluent: 2.5ml (all sizes) Sterile Water; Mix2 Device	Diluent: 4 ml (all sizes) Sodium Chloride prefilled syringe; vial adapter; 23g infusion set, alcohol pads; bandaid; gauze	Diluent: 5 ml (all sizes) Sterile Water; Baxject Mixing Device	Diluent: 4 ml (all sizes) Sodium Chloride prefilled syringe; vial adapter; 23g infusion set, alcohol pads; bandaid; gauze
<i>Storage Requirements</i>	Refrigerate or store at room temperature	Refrigerate or store at room temperature for up to 3 months		Refrigerate or store at room temperature for up to 3 months	Refrigerate or store at room temperature up to 6 months	Refrigerate or store at room temperature for up to 3 months
<i>Additional Comments</i>		Same product, can be mixed together in same syringe.		Special lab assays required		
		Due to low volume diluent, use caution in extracting all product from vial; flush line with saline or use microbore winged infusion set.				
<b>Recombinant technology may be the ONLY product of choice for patients of Jehovah Witness faith.</b>						

(1) first generation: human or animal albumin used as both nutrient in cell culture and as stabilizer in final bottle

(2) second generation: human albumin used as nutrient in cell culture but not as stabilizer in final bottle

(3) third generation: no human or animal albumin used either as nutrient in cell culture or as stabilizer in final bottle.

(4) specific viral inactivation procedures are not used, but some of the manufacturing or purification steps have virus reduction or removal capability.