US Hemophilia Clotting Factor Brands by Company and Type

MANUFACTURER	RECOMBINANT			PLASMA-DERIVED		
	FVIII	FIX	Inhibitor	FVIII	FIX	Inhibitor
Medexus Pharma, Inc.		Ixinity®				
Bayer	Kovaltry® Jivi®					
CSL Behring	Afstyla®	Idelvion®		Humate-P®		
Grifols				Alphanate®	AlphaNine®S/D Profilnine®	
HEMA Biologics, LLC[1]			Sevenfact®[2]			
Kedrion[3]				Koate®-DVI		
Novo Nordisk	Novoeight® Esperoct®	Rebinyn®	NovoSeven®RT			
Octapharma	Nuwiq®			wilate®		
Pfizer	Xyntha®	BeneFIX®				
Sanofi	Eloctate® Altuviiio™	Alprolix®				
Takeda	Advate Adynovate Recombinate	Rixubis		Hemofil M	Proplex-T	FEIBA

Commercial clotting factor concentrates are either derived from human blood plasma or are "recombinant." Recombinant products are produced by genetically engineered cells into which the human gene for factor has been inserted. These cells, called a "cell line," are then grown to large numbers in tanks containing a liquid "growth medium." The cells express the human factor into the growth medium, from which it is then extracted, concentrated and purified.

Recombinant factor concentrates may be further classified by half-life—either standard or extended half-life—and by "generation," based on the presence of human or animal proteins in the manufacturing process or final product. *First-generation* concentrates contain added animal or human proteins in the cell line growth medium and are stabilized with human albumin. *Second-generation* products contain added animal or human proteins in the growth medium but are stabilized with a sugar instead of albumin in the final formulation. *Third-generation* products are manufactured without additional human or animal plasma proteins in the growth medium or final product. *Fourth-generation* products use human cell lines (instead of hamster cell lines) to produce the factor and are manufactured without additional human or animal plasma proteins in the growth medium or final product. Third and fourth generation recombinant products eliminate the possibility of contamination with blood-borne pathogens, such as viruses.

Recombinate is a first-generation recombinant product. NovoSeven RT is a second-generation recombinant product. Advate, Adynovate, Afstyla, BeneFIX, Esperoct, Idelvion, Ixinity, Jivi, Kovaltry, Novoeight, Rebinyn, Rixubis, and Xyntha are third-generation recombinant products. Alprolix, Altuviiio, Eloctate and Nuwiq and are fourth-generation recombinant products.

Green-colored brand names in the table indicate extended half-life products (they last longer in the bloodstream). Because there is no consensus on what constitutes an extended half-life product, check the package insert (PI) carefully when comparing the half-life of products. The half-life of a product may also vary widely from patient to patient, and may vary widely with age (younger=shorter half-life; older=longer half-life). Pharmacokinetic (PK) testing can be done to determine your individual factor half-life. Discuss with your hemophilia treatment center hematologist which product best meets your needs.

1. HEMA Biologics distributes Sevenfact in the US for LFB S.A. (Laboratoire Français du Fractionnement et des Biotechnologies, South America), which is the manufacturer.
2. Sevenfact is produced by rabbits which have been genetically engineered to secrete human factor VIIa in their milk.
3. Kedrion distributes Koate-DVI in the US for Grifols, which is the manufacturer.

Novel (Non-factor) Hemophilia Therapies

Manufacturer	Product	Type	Indication
Genentech	Hemlibra®	A bispecific antibody which mimics the function of factor VIII. Administered subcutaneously (under the skin) weekly, biweekly or monthly.	Routine prophylaxis in adults and children with **hemophilia A**, (congenital factor VIII deficiency) with or without factor VIII inhibitors.*

* For those with inhibitors using Hemlibra (emicizumab-kxwh): use of more than 100 U/kg total of aPCC (FEIBA®) within 24 hours for treating breakthrough bleeds increases risk of blood clots. Consult your hematologist before using FEIBA when on Hemlibra.

Hemophilia Gene Therapies

Manufacturer	Product	Type	Indication
CSL Behring*	Hemgenix®	Gene addition using an adeno-associated virus type 5 vector (AAV5) to deliver copies of the Padua variant of human coagulation factor IX to the liver.	Treatment of adults with **hemophilia B** (congenital factor IX deficiency) who: currently use factor IX prophylaxis therapy; have current or historical life-threatening hemorrhage; or have repeated, serious spontaneous bleeding episodes. (In other words, individuals with severe hemophilia B.)

BioMarin Pharmaceutical Inc.	Roctavian™	Gene addition using an adeno-associated virus type 5 vector (AAV5) to deliver copies of a genetically engineered form of factor VIII to the liver.	Treatment of adults with severe **hemophilia A** (congenital factor VIII deficiency) without antibodies to adeno-associated virus serotype 5 (AAV5). Administered as single, one-time dose by intravenous infusion.

*HemgenIX (etranacogene dezaparvovec-drlb) is manufactured for CSL Behring in Massachusetts by uniQure NV, a Dutch gene therapy company.

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