

## Chapter 5: Concentrates for Hemostatic Disorders and Hereditary Angioedema

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### BACKGROUND

Coagulation factor concentrates are highly effective treatments for patients with hemostatic disorders caused by missing or defective clotting factors. Coagulation factor concentrates may be extracted from pooled donated plasma (plasma-derived) or manufactured using biotechnology (recombinant). In addition, several plasma-derived protein concentrates are available for the treatment of thrombotic disorders and hereditary angioedema.

These factor concentrates available to Canadian patients, as either licensed or unlicensed products, are listed in Table 1. The unlicensed products, and some licensed products that have not undergone Health Canada batch release, can be obtained under the Health Canada Special Access Program (SAP) (see legend in Table 1).

**Table 1:** Concentrates for hemostasis or hereditary angioedema, available or potentially available in Canada (see footnote for ordering information and dosage calculation)

N <sup>o</sup>	Factor concentrate	Manufacturer	Specific viral inactivation/partitioning procedures	Maximum specific activity (IU/mg protein)	Storage temp. (°C)/max RCT(°C) x (months of storage) #	Average in vitro recovery (WBCs) IU/mL per IU/kg infused‡	Average T <sub>1/2</sub> (h)	Comments
<b>Factor VIII recombinant (rFVIII), human – standard half-life</b>								
1	Kovaltry™ †	Bayer Inc.	Solvent detergent/ nanofiltration	~ 4,000	2–8/25 (12)	2	13.8	Full length FVIII, no VWF
2	Xyntha™ †	Pfizer	Solvent detergent/ nanofiltration	5,500–9,900	2–8/25 (13)	2.33	14.8	B-domain deleted FVIII, no VWF
3	Advate †	Shire	Solvent detergent	4,000–10,000	2–8/30 (8)	2.40	11.98	Full length FVIII, no VWF
4	Nuwig™ †	Octapharma	Solvent detergent/ nanofiltration	8,124	2–8/25 (11)	2.34	17.1 (age ≥12y) 12.3 (age <12y)	B-domain deleted, no VWF
5	Zenovate®† (distributed by H�ma-Qu�bec only)	Novo Nordisk	Solvent detergent/nanofiltration	8,300	2–8/30 (12)	1.9 (age ≥12y) 2.0 (age 6–11y) 1.8 (age <6y)	10.69 (age ≥12y) 8.92 (age 6–11y) 7.65 (age <6y)	B-domain deleted, no VWF
<b>Factor VIII, plasma-derived (pd FVIII) – standard half-life</b>								
6	Hemofil M †	Shire	Solvent detergent/ nanofiltration	2–22 (2,000 if albumin excluded)	2–30	2.0	14.8	High purity pdFVIII, full length FVIII, no VWF, formulated with albumin
7	Koate®-DVI †	Grifols	Solvent detergent/ terminal dry heat	9–22	2–8/25 (8)	2.0	16.12	pd full length FVIII, contains VWF (VWF:FVIII ratio = 1:1.1), formulated with albumin
<b>Factor VIII recombinant – extended half-life</b>								

<https://prof.edu.blood.ca/en/transfusion/clinical-guide/concentrates-hemostatic-disorders-and-hereditary-angioedema>

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**Important disclaimer:** This material is an educational tool providing guidelines for the care of patients. These recommendations should thus not be applied rigidly, since they could result in some patients receiving unnecessary transfusions or experiencing adverse effects from under-transfusion. The guidelines are mainly for **adult patients** and may not necessarily apply to the treatment of children. The recommendations do not replace the need in some cases to consult an expert in Transfusion Medicine to provide optimal patient care.

# Clinical Guide To Transfusion

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