

## RECOMBINANT FACTOR VIII COMPARISON CHART

Product	Cell line, molecule	Half-life	Viral inactivation	Vial size	Reconstitution device	Storage	Availability
<b>Advate</b> Manufactured and distributed by Shire	Produced in a Chinese hamster ovary (CHO) cell line.  Full-length factor VIII molecule.	Mean half-life of 13 hours in adults	Solvent detergent: Polysorbate 80	250 500 1,000 1,500 2,000 3,000 IUs	BAXJECT II	2-8°C, room temperature up to 28°C for up to 6 months	Licensed by Health Canada for all ages.  Advate was phased out in Quebec starting in April 2018.  It was phased out in the rest of Canada in 2016.

### Comments

Product monograph: [www.baxter.ca/en/downloads/product\\_information/ADVATE\\_PM\\_Dec2013\\_EN.pdf](http://www.baxter.ca/en/downloads/product_information/ADVATE_PM_Dec2013_EN.pdf)

Product	Cell line, molecule	Half-life	Viral inactivation	Vial size	Reconstitution device	Storage	Availability
<b>Adynovate</b> Manufactured and distributed by Shire	Produced in a Chinese hamster ovary (CHO) cell line	Covalently conjugated with a 20 kDa polyethylene glycol (PEG) reagent to increase half-life.  Mean half-life in adults of 1.4 to 1.5 times that of Advate.	Solvent detergent: Polysorbate 80	250 500 1,000 2,000 IUs	Reconstituted with Baxject II in 5 mL of diluent	2-8°C. May be stored at room temperature not to exceed 30°C for a period of up to 3 months	Licensed by Health Canada in 2017 for the control and prevention of bleeding episodes, routine prophylaxis and surgery for patients 12 years of age and older.  Approved by Health Canada in November 2018 for patients under 12 years of age for the same indications.  Available as of April 1, 2018 in all provinces except Quebec.

### Comments

Product monograph: [www.shirecanada.com/-/media/shire/shireglobal/shirecanada/pdf/files/product%20information/adynovate-pm-en.pdf](http://www.shirecanada.com/-/media/shire/shireglobal/shirecanada/pdf/files/product%20information/adynovate-pm-en.pdf)

Product	Cell line, molecule	Half-life	Viral inactivation	Vial size	Reconstitution device	Storage	Availability
<p><b>Afstyla</b> Antihemophilic Factor VIII (Recombinant), SingleChain manufactured and distributed by CSL Behring</p>	<p>Produced in a Chinese hamster ovary (CHO) cell line.</p> <p>B-domain-deleted factor VIII molecule.</p> <p>The single-chain design results in high binding affinity of Afstyla to von Willebrand factor.</p>	<p>Mean half-life of 14 hours in adults</p>	<p>Nanofiltration</p> <p>Solvent detergent: Polysorbate 80</p>	<p>250 IUs (2.5 mL)</p> <p>500 IUs (2.5 mL)</p> <p>1,000 IUs (2.5 mL)</p> <p>1,500 IUs (5 mL)</p> <p>2,000 IUs (5 mL)</p> <p>3,000 IUs (5 mL)</p>	<p>Mix2Vial</p>	<p>2-8°C, room temperature up to 25°C for up to 3 months</p>	<p>Licensed by Health Canada for all adults and children to control and prevent bleeds, for prophylaxis and for surgery.</p> <p>Not distributed in Canada.</p>

**Comments**

Product monograph: <http://labeling.cslbehring.ca/PM/CA/AFSTYLA/EN/AFSTYLA-Product-Monograph.pdf>

Product	Cell line, molecule	Half-life	Viral inactivation	Vial size	Reconstitution device	Storage	Availability
<p><b>Eloctate</b> Manufactured and distributed by Bioverativ/Sanofi</p>	<p>Produced in a human embryonic kidney (HEK) cell line.</p> <p>B-domain deleted FVIII molecule linked to the Fc domain of human immunoglobulin to extend half-life.</p>	<p>Mean half-life of 19 hours in adults, 1.5 times that of standard half-life products</p>	<p>Detergent viral inactivation step and multiple viral clearance steps, including an affinity chromatography step and a 15 nm virus-retaining nanofiltration step</p>	<p>250 500 750 1,000 1,500 2,000 3,000 IUs</p>	<p>3 mL diluent in prefilled syringe, provided with 1 infusion set, 2 alcohol pads, 1 gauze pad, and 2 bandages</p>	<p>2-8°C for 30 months, room temperature up to 30°C for a single period of up to 6 months</p>	<p>Approved by Health Canada and indicated in adults and children for routine prophylaxis, control and prevention of bleeds and for surgery.</p> <p>Available on a limited basis for specific needs (short half-life, venous access difficulties, other medically justified reasons) in Quebec.</p> <p>In the rest of Canada, as of February 2019, Eloctate is available only via the exceptional patient access process on a case by case basis for medically justified reasons.</p>

**Comments**

Health Canada Basis of Decision: [www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/drug-med/sbd\\_smd\\_2014\\_eloctate\\_163447-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/drug-med/sbd_smd_2014_eloctate_163447-eng.php)

Product monograph: [www.bioverativ.ca/Files/Files/Corporate/ca\\_EN/pdfs/2017\\_10\\_06\\_Eloctate\\_PM\\_E.pdf](http://www.bioverativ.ca/Files/Files/Corporate/ca_EN/pdfs/2017_10_06_Eloctate_PM_E.pdf)

Product	Cell line, molecule	Half-life	Viral inactivation	Vial size	Reconstitution device	Storage	Availability
<b>Esperoct</b> Turoctocog alfa pegol, Manufactured and distributed by Novo Nordisk	Produced in a Chinese Hamster Ovary (CHO) cell line.  B-domain truncated FVIII molecule, PEGylated (40 kDa polyethylene-glycol) to extend half-life	Mean half-life of 19 hours in adults, 1.5 times that of standard half-life products	Detergent viral inactivation step and multiple viral clearance steps, including an affinity chromatography step and a 20 nm virus-retaining nanofiltration step	500 1,000 1,500 2,000 3,000 IUs	4 mL diluent in prefilled syringe, with MixPro reconstitution device	2-8°C up to expiry date, up to 30°C for a single period not exceeding 12 months	Approved by Health Canada and indicated in adults and children for routine prophylaxis, control and prevention of bleeds and for surgery.  Not distributed in Quebec or the rest of Canada.

#### Comments

Health Canada Basis of Decision: <https://hpr-rps.hres.ca/reg-content/regulatory-decision-summary-detail.php?lang=en&linkID=RDS00570>

Product monograph: [www.novonordisk.ca/content/dam/Canada/AFFILIATE/www-novonordisk-ca/OurProducts/PDF/esperoct-product-monograph.pdf](http://www.novonordisk.ca/content/dam/Canada/AFFILIATE/www-novonordisk-ca/OurProducts/PDF/esperoct-product-monograph.pdf)

Product	Cell line, molecule	Half-life	Viral inactivation	Vial size	Reconstitution device	Storage	Availability
<b>Jivi</b> Manufactured by Bayer	Produced in a baby hamster kidney (BHK) cell line.  B-domain deleted factor VIII molecule.  60 kilodalton dual-branched PEG molecule is conjugated at the A3 domain.	Mean half-life of 1.4 to 1.5 times that of Kogenate, or 18-19 hours in adults, obtained by PEGylation	Chromatography, filtration and ultrafiltration	250 500 1,000 2,000 3,000 IUs	Vial Adapter, 2.5 mL of diluent for all vial sizes	2-8°C, can be stored up to 25°C for up to 6 months, or up to 30°C for 3 months	Approved by Health Canada in October 2018 for prophylaxis, on-demand control of bleeding and surgery for patients with hemophilia A 12 years of age and older.  While not distributed in Quebec, Jivi is available in the rest of Canada.

#### Comments

Product monograph: [https://pdf.hres.ca/dpd\\_pm/00047833.PDF](https://pdf.hres.ca/dpd_pm/00047833.PDF)

Product	Cell line, molecule	Half-life	Viral inactivation	Vial size	Reconstitution device	Storage	Availability
<b>Kovaltry</b> Manufactured and distributed by Bayer	Produced in a baby hamster kidney (BHK) cell line. Full-length factor VIII molecule.	Mean half-life of 13-14 hours in adults	Detergent virus inactivation step, 20-nm filtration step	250 500 1,000 IUs with 2.5 mL diluent 2,000 3,000 IUs with 5 mL diluent	Vial Adapter	2-8°C, room temperature up to 25°C for up to 12 months	Approved by Health Canada in 2016 for the treatment and prophylaxis of bleeding, and surgery in patients of all ages.  Not currently distributed in Québec.  Available in rest of Canada.

#### Comments

Health Canada Basis of Decision: [www.hc-sc.gc.ca/dhp-mps/prodpharma/rds-sdr/drug-med/rds-sdr-kovaltry-181693-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/rds-sdr/drug-med/rds-sdr-kovaltry-181693-eng.php)

Product monograph: <http://omr.bayer.ca/omr/online/kovaltry-pm-en.pdf>

Product	Cell line, molecule	Half-life	Viral inactivation	Vial size	Reconstitution device	Storage	Availability
<b>Nuwiq</b> Manufactured and distributed by Octapharma	Produced in a human embryonic kidney (HEK) cell line. B-domain deleted FVIII molecule.	Mean half-life of 14 hours in adults	A series of chromatography purification steps, virus inactivation, further purification by chromatography, a second dedicated viral removal step by nanofiltration, and a final purification step by size exclusion chromatography	250 500 1,000 2,000 3,000 4,000 IUs	2.5 mL diluent	2 to 8°C for up to 18 months, room temperature up to 25°C for up to 1 month	Approved by Health Canada for the treatment and prophylaxis of bleeding in patients of all ages.  Nuwiq was introduced in Quebec as of April 1, 2018 without restrictions.  Also available in rest of Canada.

#### Comments

Health Canada Basis of Decision: [www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/drug-med/sbd\\_smd\\_2015\\_nuwiq\\_169551-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/drug-med/sbd_smd_2015_nuwiq_169551-eng.php)

Product monograph: [www.octapharma.ca/fileadmin/user\\_upload/octapharma.ca/Product\\_Monographs/PM00031489\\_Nuwiq\\_EN.PDF](http://www.octapharma.ca/fileadmin/user_upload/octapharma.ca/Product_Monographs/PM00031489_Nuwiq_EN.PDF)

Product	Cell line, molecule	Half-life	Viral inactivation	Vial size	Reconstitution device	Storage	Availability
<b>Xyntha</b> Manufactured and distributed by Pfizer	Produced in a Chinese hamster ovary (CHO) cell line. B-domain-deleted factor VIII molecule.	Mean half-life of 11-12 hours in adults	Nanofiltration Solvent detergent: Polysorbate 80	250 500 1,000 2,000 3,000 IUs	R2 Kit Xyntha Solofuse all-in-one reconstitution device	2-8°C, room temperature up to 25°C for up to 3 months	Licensed by Health Canada for all ages. Currently distributed in all provinces, but Xyntha is being phased out in Quebec as of April 2018.

#### Comments

Product monograph: [www.pfizer.ca/sites/g/files/g10017036/f/201505/XYNTHA\\_PM\\_E\\_177952\\_12Jan2015.pdf](http://www.pfizer.ca/sites/g/files/g10017036/f/201505/XYNTHA_PM_E_177952_12Jan2015.pdf)

Product	Cell line, molecule	Half-life	Viral inactivation	Vial size	Reconstitution device	Storage	Availability
<b>Zonovate</b> (NovoEight in the rest of the world) Manufactured and distributed by Novo Nordisk	Produced in a Chinese hamster ovary (CHO) cell line. B-domain truncated FVIII molecule.	Mean half-life of 11-12 hours in adults	Purification steps include chromatography using a FVIII specific monoclonal antibody (mAb) immune affinity column and sterile filtration	250 500 1,000 1,500 2,000 3,000 IUs	MixPro with 4 mL diluent	2-8°C for 24 months, room temperature up to 30°C for a single period of up to 12 months	Approved by Health Canada for the peri-operative management treatment and prophylaxis of bleeding in patients of all ages. Not currently distributed by CBS. Zonovate was introduced in Quebec as of April 1, 2018 without restrictions.

#### Comments

Health Canada Basis of Decision: [www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/drug-med/sbd\\_smd\\_2015\\_zonovate\\_170796-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/drug-med/sbd_smd_2015_zonovate_170796-eng.php)

Product monograph: [www.novonordisk.ca/content/dam/Canada/AFFILIATE/www-novonordisk-ca/OurProducts/PDF/Zonovate\\_PM\\_English.pdf](http://www.novonordisk.ca/content/dam/Canada/AFFILIATE/www-novonordisk-ca/OurProducts/PDF/Zonovate_PM_English.pdf)

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