

RECOMBINANT FACTOR VIII COMPARISON CHART

Product	Cell line, molecule	Half-life	Viral inactivation	Vial size	Reconstitution device	Storage	Availability
Advate 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. Currently available in Quebec, but will be phased out starting in April 2018. Phased out in rest of Canada in 2016.

Comments

Product monograph: 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
Adynovate 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. Available as of April 1, 2018 in all provinces except Quebec. Indicated in patients 12 years and older for the control and prevention of bleeding episodes, routine prophylaxis and surgery.

Comments

Product monograph: 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>Afstyla 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>Eloctate Manufactured and distributed by Bioverativ</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) in Quebec.</p> <p>Currently available for most patients in rest of Canada. As of April 1, 2018, Eloctate will be available only for patients under 12 years of age, those on prophylaxis with less than 100 exposure days and those continuing immune tolerance therapy.</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

Product monograph: 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
<p>Helixate FS Manufactured by Bayer and distributed by CSL Behring</p>	<p>Produced in a baby hamster kidney (BHK) cell line.</p> <p>Full-length factor VIII molecule.</p>	<p>Mean half-life of 12 hours in adults</p>	<p>Solvent detergent: TNBP/Polysorbate 80</p>	<p>250 500 1,000 2,000 IUs</p>	<p>Mix2Vial</p>	<p>2-8°C, room temperature up to 25°C for up to 12 months</p>	<p>Licensed, but no longer distributed by CBS or Héma-Québec.</p>

Comments

Product monograph: <http://labeling.csllbehring.ca/PM/CA/HelixateFS/EN/Helixate-FS-Product-Monograph.pdf>

Product	Cell line, molecule	Half-life	Viral inactivation	Vial size	Reconstitution device	Storage	Availability
Kovaltry 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	BIO-SET	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

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
Nuwiq 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 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 will be introduced in Quebec starting 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

Product monograph: 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
Xyntha 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 will be phased out in Quebec starting in April 2018.

Comments

Product monograph: 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
Zonovate (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 will be introduced in Quebec starting 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

Product monograph: www.novonordisk.ca/content/dam/Canada/AFFILIATE/www-novonordisk-ca/OurProducts/PDF/Zonovate_PM_English.pdf

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