

COAGULATION PRODUCTS FOR HEMOPHILIA A

Recombinant factor VIII comparison chart

Product	Cell line, molecule	Half-life	Viral inactivation	Vial size	Reconstitution device	Storage	Availability
<p>Adynovate Manufactured and distributed by Takeda</p>	<p>Produced in a Chinese hamster ovary (CHO) cell line</p>	<p>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.</p>	<p>Solvent detergent: Polysorbate 80</p>	<p>250 500 1,000 2,000 IUs</p>	<p>Reconstituted with Baxject II in 5 mL of diluent</p>	<p>2-8°C. May be stored at room temperature not to exceed 30°C for a period of up to 3 months</p>	<p>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 without restrictions as of April 1, 2018 in all provinces except Quebec.</p>

Comments

Product monograph: www.takeda.com/4ab39a/siteassets/en-ca/home/what-we-do/our-medicines/product-monographs/adynovate/adynovate-pm-en.pdf

Product	Cell line, molecule	Half-life	Viral inactivation	Vial size	Reconstitution device	Storage	Availability
<p>Eloctate Manufactured and distributed by Sanofi Genzyme</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 April 1, 2022, Eloctate is available without restrictions.</p>

Comments

Product monograph: www.sanofi.com/assets/countries/canada/docs/products/prescription-products/eloclate-en.pdf

Product	Cell line, molecule	Half-life	Viral inactivation	Vial size	Reconstitution device	Storage	Availability
<p>Esperoct Turoctocog alfa pegol, Manufactured and distributed by Novo Nordisk</p>	<p>Produced in a Chinese Hamster Ovary (CHO) cell line.</p> <p>B-domain truncated FVIII molecule, PEGylated (40 kDa polyethylene-glycol) 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 20 nm virus-retaining nanofiltration step</p>	<p>500 1,000 1,500 2,000 3,000 IUs</p>	<p>4 mL diluent in prefilled syringe, with MixPro reconstitution device</p>	<p>2-8°C up to expiry date, up to 30°C for a single period not exceeding 12 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>Esperoct will be available in Quebec without restrictions as of April 1, 2023. In the rest of Canada, as of April 1, 2022, Esperoct is available without restrictions.</p>

Comments

Product monograph: 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
Jivi 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, as of April 1, 2022, Jivi is available in the rest of Canada without restrictions (except for age).

Comments

Product monograph: www.bayer.com/sites/default/files/2020-11/jivi-pm-en.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	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 the rest of Canada without restrictions.

Comments

Product monograph: www.bayer.com/sites/default/files/2020-11/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 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 but will be phased out starting April 1, 2023. In the rest of Canada, Nuwiq was phased out in 2022.

Comments

Product monograph: https://pdf.hres.ca/dpd_pm/00044390.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. Xyntha was phased out in Quebec as of April 2018. It is currently distributed in the rest of Canada without restrictions.

Comments

Product monograph: www.pfizer.ca/sites/default/files/201710/XYNTHA_PM_191983_28Apr2016_E.pdf

Product	Cell line, molecule	Half-life	Viral inactivation	Vial size	Reconstitution device	Storage	Availability
<p>Zonovate (NovoEight in the rest of the world) Manufactured and distributed by Novo Nordisk</p>	<p>Produced in a Chinese hamster ovary (CHO) cell line. B-domain truncated FVIII molecule.</p>	<p>Mean half-life of 11-12 hours in adults</p>	<p>Purification steps include chromatography using a FVIII specific monoclonal antibody (mAb) immune affinity column and sterile filtration</p>	<p>250 500 1,000 1,500 2,000 3,000 IUs</p>	<p>MixPro with 4 mL diluent</p>	<p>2-8°C for 24 months, room temperature up to 30°C for a single period of up to 12 months</p>	<p>Approved by Health Canada for the peri-operative management treatment and prophylaxis of bleeding in patients of all ages. Zonovate is approved for use by CBS but not currently distributed. Zonovate was introduced in Quebec as of April 1, 2018 without restrictions but was phased out as of April 1, 2023.</p>

Comments

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

Non-factor replacement therapies to treat patients with hemophilia A without inhibitors

Product	Company	Type	Administration	Description	Storage	Availability	Warnings
Hemlibra (also called emicizumab)	Roche Canada (Hoffmann La Roche)	Bispecific monoclonal antibody	Subcutaneously, once every 1, 2 or 4 weeks	Hemlibra is a bispecific antibody that mimics coagulation factor VIII with a half-life of 28 days. It offers an alternative to factor VIII for patients with hemophilia A, through subcutaneous routine prophylaxis. In clinical trials, it has been shown to decrease annual bleeding rates compared to FVIII prophylaxis. Hemlibra cannot be used to treat active bleeding; factor VIII is recommended in this event.	Store at 2-8°C. Do not freeze. Do not shake. Keep the vial in the outer carton in order to protect from light. Once removed from the refrigerator, unopened vials can be kept at room temperature (below 30°C) for up to 7 days.	On June 14, 2019, Health Canada approved an indication for patients with hemophilia A without inhibitors. On April 1, 2022, access was granted in Quebec to all those, regardless of age, with severe or moderately severe hemophilia A requiring prophylaxis. In the rest of Canada, access was granted in September 2021 to those with severe hemophilia A (baseline FVIII level of <1%), without additional restrictions.	The product monograph contains a Health Canada warning. Serious adverse reactions have been reported when on average a cumulative amount of >100 IU/kg/24 hours of activated prothrombin complex concentrate (aPCC/FEIBA) was administered for 24 hours or more to patients receiving Hemlibra prophylaxis. FEIBA is only used in the treatment of those with an inhibitor.

Comments

Product monograph: www.rochecanada.com/PMs/Hemlibra/Hemlibra_PM_E.pdf

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