RECOMBINANT FACTOR IX

Product	Cell line, molecule	Half-life, recovery	Viral inactivation	Vial size	Reconstitution device	Storage	Availability
Alprolix Manufactured and distributed by Bioverativ	Produced in a human embryonic kidney (HEK) cell line. Covalently linked to the Fc domain of recombinant human immunoglobulin G1 to extend half-life.	Half-life is 2.5 times longer than Benefix, permitting once-a-week infusions. Recovery is similar to Benefix.	Multiple viral clearance steps including 15 nm virus-retaining nano-filtration	250 500 1,000 2,000 3,000 IUs	Diluent provided in prefilled syringe (5 mL of diluent)	2°C to 8°C or up to 30°C for a single 6-month period	Licensed by Health Canada in 2014 for all ages. Distributed on a limited basis for newly diagnosed babies and for patients with specific needs (short half-life, venous access problems, other demonstrated medical need) in Quebec. In the rest of Canada, Alprolix is available only for patients under 18 years of age.
Comments							
Health Canada Basis of Decision: **www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/drug-med/sbd_smd_2014_alprolix_163614-eng.php** Product monograph: **www.bioverativ.ca/Files/Files/Corporate/ca_EN/pdfs/2018_01_30_Alprolix_PM_E.PDF**							

Product	Cell line, molecule	Half-life, recovery	Viral inactivation	Vial size	Reconstitution device	Storage	Availability
Benefix Manufactured and distributed by Pfizer	Produced in a Chinese hamster ovary (CHO) cell line	Mean half-life of 19 hours in adults. 28% lower in-vivo recovery than with plasma-derived FIX.	Solvent detergent: Polysorbate 80	250 500 1,000 1,500 2,000 3,000 IUs	Diluent provided in prefilled syringe (5 mL of diluent)	Room temperature or under refrigeration, at a temperature of 2°C to 30°C	Licensed by Health Canada in 1997. Distributed in all provinces except Quebec. Indicated for the control and prevention of bleeding and for routine prophylaxis and surgery in patients of all ages.
Comments							
Product monograph: **www.pfizer.ca/sites/g/files/g10017036/f/201410/BENEFIX_PM_E_153056_27Dec2012.pdf**							

Product	Cell line, molecule	Half-life, recovery	Viral inactivation	Vial size	Reconstitution device	Storage	Availability
Idelvion Manufactured and distributed by CSL Behring	Produced in a Chinese hamster ovary (CHO) cell line. Fused to recombinant human albumin to extend half-life.	Half-life is 5 to 6 times longer than Benefix, permitting once-a-week infusions or less frequently. Recovery is superior to Benefix.	Two dedicated, orthogonal virus reduction steps including nanofiltration	250 500 1,000 2,000 IUs	Mix2Vial (2.5 mL of diluent for 250, 500 and 1,000 IU vials; 5 mL diluent for 2,000 IU vial)	Between 2°C and 25°C	Licensed by Health Canada in 2016 for treatment of bleeding, prophylaxis and surgery for all ages. Available in Quebec for newly diagnosed babies and for patients who meet strict criteria (short half-life, venous access difficulty, other demonstrated medical need). Not currently available in the rest of Canada.
Comments							
Health Canada Basis of Decision: **www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/drug-med/sbd-smd-2016-idelvion-180793-eng.php** Product monograph: **http://labeling.cslbehring.ca/PM/CA/IDELVION/EN/IDELVION-Product-Monograph.pdf**							

Product	Cell line, molecule	Half-life, recovery	Viral inactivation	Vial size	Reconstitution device	Storage	Availability
Rebinyn Manufactured and distributed by Novo Nordisk	Produced in a Chinese hamster ovary (CHO) cell line Half-life extended by conjugation with 40-kDa polyethylene glycol (PEG)	Half-life 5 times longer than Benefix; Recovery close to 2 times higher than Benefix	Solvent detergent and 20 nm nano-filtration	500 1,000 2,000 IUs	MixPro pre-filled syringe (4 mL of diluent)	2°C to 8°C up to expiry date Room temperature not to exceed 30°C for up to 6 months	Licensed by Health Canada in November 2017 for adults and children to control and prevent bleeding and for surgery. Not indicated for routine prophylaxis in patients under 18 years. Rebinyn was introduced in all provinces except Quebec as of April 2018 and is routinely used for prophylaxis in all ages.

Comments

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

Product	Cell line, molecule	Half-life, recovery	Viral inactivation	Vial size	Reconstitution device	Storage	Availability
Rixubis Manufactured and distributed by Shire	Produced in a Chinese hamster ovary (CHO) cell line	Standard half-life similar to Benefix Recovery similar to Benefix	Solvent detergent and 15 nm nano-filtration	250 500 1,000 2,000 3,000 IUs	BAXJECT II (5 mL of diluent)	2°C to 8°C for up to 24 months Room temperature not to exceed 30°C for up to 12 months	Licensed by Health Canada in 2015 for adults to control bleeding and for prophylaxis and surgery. Rixubis is routinely available in Quebec. Not distributed in rest of Canada.

Comments

Product monograph: **www.baxalta.ca/downloads/Product_Monographs/en/Rixubis.pdf**

Last revised – September 2, 2020