

RECOMBINANT FACTOR IX

Product	Cell line, molecule	Half-life, recovery	Viral inactivation	Vial size	Reconstitution device	Storage	Availability
<p>Alprolix Manufactured and distributed by Biogen Idec</p>	<p>Produced in a human embryonic kidney (HEK) cell line.</p> <p>Covalently linked to the Fc domain of recombinant human immunoglobulin G1 to extend half-life.</p>	<p>Half-life is 2.5 times longer than Benefix, permitting once-a-week infusions.</p> <p>Recovery is similar to Benefix.</p>	<p>Multiple viral clearance steps including 15 nm virus-retaining nano-filtration</p>	<p>250</p> <p>500</p> <p>1,000</p> <p>2,000</p> <p>3,000 IUs</p>	<p>Diluent provided in prefilled syringe (5 mL of diluent)</p>	<p>2°C to 8°C or up to 30°C for a single 6-month period</p>	<p>Licensed by Health Canada in 2014 for children and adults 12 years and older.</p> <p>Distributed on a limited basis for specific needs (short half-life, venous access problems) in Quebec.</p> <p>Available for most patients in rest of Canada. As of April 1, 2018, Alprolix will be available only for patients under 18 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_alprolix_163614-eng.php

Product monograph: www.biogen.ca/content/dam/corporate/en_CA/pdfs/products/ALPROLIX/Alprolix-Product-Monograph-19Nov2015_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. Distribution of Benefix in Quebec was phased out starting in April 2017. 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. Not currently available in 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 will be introduced in all provinces except Quebec starting in April 2018.

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 was introduced in Quebec starting in April 2017. Not distributed in rest of Canada.

Comments

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

Last revised – February 8, 2018