

PRODUCTS TO TREAT RARE FACTOR DEFICIENCIES

Product	Plasma source	Fractionation	Viral inactivation	Vial size	Storage	Availability
Bebulin VH Manufactured by Shire	USA: volunteer, remunerated plasmapheresis donors	Ion exchange adsorption	Vapour heat @ 60°C for 10 hr at 190 mbar, then 80°C for 1 hr @ 375 mbar	600 IUs	2-8°C	Available through Special Access Programme. Distributed in all provinces.

Comments

Factor IX complex containing factors II, VII, IX and X, heparin added.

Product	Plasma source	Fractionation	Viral inactivation	Vial size	Storage	Availability
Coagadex® Manufactured by Bio Products Laboratory (BPL)	USA: volunteer, remunerated plasmapheresis donors		Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses.	250 IUs of FX (2.5 mL) 500 IUs of FX (2.5 mL)	Shelf life of three years at under 30°C	Coagadex is a high-purity factor X concentrate. It is approved by the U.S. FDA, and is indicated in adults and children (aged 12 years and above) with hereditary factor X deficiency for on-demand treatment and control of bleeding episodes, and perioperative management of bleeding in patients with hereditary factor X deficiency. Not currently available in Canada.

Comments

Summary of product characteristics: www.medicines.org.uk/emc/medicine/31626.

Product	Plasma source	Fractionation	Viral inactivation	Vial size	Storage	Availability
Corifact Manufactured by CSL Behring	USA: volunteer, remunerated plasmapheresis donors	Multiple precipitation	Purification steps: 1) Precipitation/adsorption 2) Ion exchange chromatography 3) Heat-treatment (+60°C for 10 hours in an aqueous solution) 4) Virus filtration over two 20 nm filters in series	250 IUs (4 mL of diluent) 1,250 IUs (20 mL of diluent) Mix2Vial	2-8°C	Licensed by Health Canada. Distributed in all provinces.

Comments

Indicated for routine prophylaxis and peri-operative management of surgical bleeding in patients with congenital factor XIII deficiency.

Product	Plasma source	Fractionation	Viral inactivation	Vial size	Storage	Availability
Factor VII concentrate Manufactured by Shire	USA: volunteer, remunerated plasmapheresis donors	Aluminium hydroxide adsorption	Vapour heat @ 60°C for 10 hr at 190 mbar, then 80°C for 1 hr @ 375 mbar	600 IUs	2-8°C	Available through Special Access Programme. Distributed in all provinces.

Comments

Used to treat factor VII deficiency.

Product	Plasma source	Fractionation	Viral inactivation	Vial size	Storage	Availability
Factor XI concentrate Manufactured by Bio Products Laboratory (BPL)	USA: volunteer, remunerated plasmapheresis donors	Affinity heparin sepharose chromatography	Dry heat @ 80°C, 72 hr	1,000 IUs	2-8°C	Available through Special Access Programme. Distributed in all provinces. N.B. The company is currently experiencing production problems.

Comments

Sometimes used to treat factor XI deficiency, heparin and anti-thrombin III added.

Product	Plasma source	Fractionation	Viral inactivation	Vial size	Storage	Availability
NiaStase RT® Manufactured by Novo Nordisk	Recombinant factor VIIa (eptacog alfa - activated)	Not applicable	Production of NiaStase RT® via recombinant DNA technology eliminates the risks of transmission of human blood-borne pathogens such as HIV, hepatitis viruses and parvovirus.	1.0 mg (50 KIU/vial) 2.0 mg (100 KIU/vial) 5.0 mg (250 KIU/vial)	2-30°C	Licensed to treat bleeding and in surgery for patients with hemophilia A or B and inhibitors. Distributed in all provinces.

Comments

NiaStase is called NovoSeven® elsewhere in world. The European Medicines Agency has approved the use of NovoSeven for congenital factor VII deficiency.

Product	Plasma source	Fractionation	Viral inactivation	Vial size	Storage	Availability
Prothromplex-T Manufactured by Shire	USA: volunteer, remunerated plasmapheresis donors	Ion exchange adsorption	Vapour heat @ 60°C for 10 hr at 190 mbar, then 80°C for 1 hr @ 375 mbar	600 IUs	2-8°C	Available through Special Access Programme. Distributed in all provinces.

Comments

Contains factors II, VII, IX and X, used to treat prothrombin (factor II) deficiency and factor X deficiency.

Product	Plasma source	Fractionation	Viral inactivation	Vial size	Storage	Availability
RiaSTAP™ Manufactured by CSL Behring	USA: volunteer, remunerated plasmapheresis donors	Multiple precipitation absorption steps	Multiple virus inactivation and removal steps, including pasteurization @ 60°C 20 hours	1 g of human fibrinogen, reconstituted with 50 mL of sterile water	In refrigerator or at room temperature between 2°C and 25°C	Licensed by Health Canada. Distributed in all provinces.

Comments

Used to treat congenital fibrinogen deficiency which comprises congenital afibrinogenemia and hypofibrinogenemia, albumin added.

Product	Plasma source	Fractionation	Viral inactivation	Vial size	Storage	Availability
Tretten® Manufactured by Novo Nordisk	Recombinant protein manufactured without the use of human or animal proteins	Not applicable	Purification through a series of chromatography steps	2,500 IUs	2-8°C	Licensed by Health Canada. Distributed in all provinces.

Comments

Tretten (catridecacog) is indicated for routine prophylaxis for bleeding in patients with congenital factor XIII A-subunit deficiency. Should not be used for prophylactic treatment of bleeding in patients with congenital factor XIII B-subunit deficiency.

Last revised – September 2, 2020