

FACTOR PRODUCTS FOR PATIENTS WITH INHIBITORS

Product	Type	Albumin in cell culture	Albumin as stabilizer	Viral inactivation	Vial size	Storage	Availability
FEIBA NF Manufactured by Shire FEIBA is short for Factor Eight Inhibitor Bypassing Agent	Plasma-derived, USA: volunteer, remunerated plasmapheresis donors	Not applicable	Yes (human albumin)	Vapour heat, 60°C, 10 hr @ 190 mbar; then 80°C, 1 hr @ 375 mbar. Nano-filtered	400 – 1,200 units per 20 mL 1,750 – 3,250 units per 50 mL	2-8°C, room temperature up to 25° for up to 6 months	Indicated for use in hemophilia A and B patients with inhibitors for: <ol style="list-style-type: none"> 1) control of spontaneous bleeding episodes; 2) surgical interventions; 3) routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children older than 6 years of age. Distributed in all provinces.

Comments

Product monograph: www.baxter.ca/en/downloads/product_information/FEIBA_NF_PM_30Sept2014_EN.pdf

Product	Type	Albumin in cell culture	Albumin as stabilizer	Viral inactivation	Vial size	Storage	Availability
NiaStase RT® Manufactured by Novo Nordisk (NiaStase is called NovoSeven elsewhere in the world.)	Recombinant factor VIIa (eptacog alfa - activated)	Yes (bovine albumin)	No	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

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

NON-FACTOR THERAPIES TO TREAT PATIENTS WITH INHIBITORS

Product	Company	Type	Administration	Description	Storage	Availability	Warnings
Hemlibra® (previously called emicizumab and ACE-910)	Roche Canada (Hoffmann La Roche)	Monoclonal antibody	Subcutaneously, once a week	Hemlibra is a bi-specific antibody that mimics coagulation factor VIII with a half-life of three weeks. It offers an alternative option for patients with hemophilia A with inhibitors, through user-friendly, sub-cutaneous routine prophylaxis. In clinical trials, it has shown dramatic reductions in bleeding rates compared to bypassing agents.	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 August 2, 2018, Hemlibra was approved by Health Canada for use in patients with hemophilia A and inhibitors. On June 14, 2019, an additional treatment indication for patients with hemophilia A without inhibitors was granted. In May 2019, authorities in Quebec and the rest of Canada agreed to reimburse Hemlibra through Héma-Québec and CBS for the inhibitor indication. It is now available in Quebec and the rest of Canada for all patients with an inhibitor to FVIII. Access for patients with hemophilia A without an inhibitor is unlikely before 2021.	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.

Comments

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