Product Profile

ESPEROCT®

Antihemophilic Factor VIII (Recombinant, B-Domain Truncated), PEGylated turoctocog alfa pegol

TRADE NAME	ESPEROCT®
PRODUCT COMPOSITION	**Clinically Relevant Nonmedicinal Ingredients:** Calcium chloride dihydrate, L-histidine, L-methionine, polysorbate 80, sodium chloride, sucrose, sodium chloride, water for injections
ALTERNATIVES	**Non-blood product:**
	Blood product:
DOSAGE	Adults and adolescents (12 years and above): The recommended starting dose is 50 IU of ESPEROCT® per kg body weight every 4 days. Children (below 12 years): A dose of 60 IU/kg (50–75 IU) of ESPEROCT® per kg body weight administered twice weekly. The dose regimens may be individually adjusted to less or more frequent dosing based on bleeding episodes. **Refer to the ESPEROCT® Product Monograph for specific dosage guidelines for each clinical indication**
ADMINSTRATION	• ESPEROCT® should be administered by intravenous injection (over approximately 2 minutes) after reconstitution of the lyophilised powder with 4 mL 0.9% sodium chloride solvent (provided). • Do not administer reconstituted ESPEROCT® in the same tubing or container with other medications. • In case of self-administration or administration by a caregiver, appropriate training is required. **Refer to the ESPEROCT® Product Monograph for detailed information including reconstitution instructions.**

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CLINICAL/ DIAGNOSTIC MONITORING	**Monitoring and Laboratory Tests** During the course of treatment, appropriate determination of FVIII activity levels is advised to guide adjustments of the dosing regimen of ESPEROCT®, if needed. Individual patients may vary in their response to FVIII, demonstrating different half-lives and incremental recoveries. In the case of major surgical interventions in particular, monitoring of the FVIII substitution therapy by measurement of plasma FVIII activity is necessary. Monitoring of post dose FVIII activity is recommended in previously untreated patients" [see WARNINGS AND PRECAUTIONS/ Pediatrics and Clinical Trial Adverse Reactions/Previously untreated patients in the ESPEROCT® Product Monograph]. FVIII activity levels can be monitored with a validated test (one-stage clotting or chromogenic assays). FVIII activity levels can be affected by the type of activated partial thromboplastin time (aPTT) reagent used in the one-stage clotting assay. Some silica-based aPTT reagents can underestimate the activity of ESPEROCT® by approximately 50%. If an appropriate one-stage clotting or chromogenic assay is not available locally, then use of a reference laboratory is recommended. In general, all patients treated with coagulation FVIII products should be carefully monitored for the development of inhibitors by appropriate clinical observations and laboratory tests. If the expected FVIII activity plasma levels are not attained, or if bleeding is not controlled with an appropriate FVIII replacement therapy, then testing for the presence of FVIII inhibitors should be performed. In patients with high levels of inhibitor, FVIII therapy may not be effective and other therapeutic options should be considered. Management of such patients should be directed by physicians with experience in the care of hemophilia and FVIII inhibitors. **Peri-Operative Considerations** ESPEROCT® is indicated in the perioperative management of patients with hemophilia A. Careful monitoring of replacement therapy is necessary in cases of major surgery or life threatening bleeding episodes. Data on surgery are not available for children < 12 years of age.

CLINICAL INDICATIONS	• ESPEROCT® (Antihemophilic Factor VIII (Recombinant, B-Domain Truncated), PEGylated) is indicated for use in adults and children with hemophilia A (congenital Factor VIII deficiency) for:
	  ○ Routine prophylaxis to prevent or reduce the frequency of bleeding episodes
	  ○ On-demand treatment and control of bleeding episodes
	  ○ Perioperative management of bleeding.
	• ESPEROCT® is not indicated for the treatment of von Willebrand disease

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SPECIAL CONSIDERATIONS	**Pediatrics** Pediatrics (< 18 years of age): Based on the data submitted and reviewed by Health Canada, the safety and efficacy of ESPEROCT® in previously treated pediatric patients has been established; therefore, Health Canada has authorized an indication for pediatric use. Safety and efficacy were evaluated in 93 previously treated pediatric patients <18 years of age, who received at least one dose of ESPEROCT®; all received routine prophylaxis [see CLINICAL TRIALS (14.2)]. Thirty-four (34) of these subjects (36.6%) were 1 to <6 years of age; 34 subjects (36.6%) were 6 to <12 years of age; and 25 subjects (27%) were 12 to <18 years of age. The safety profile of ESPEROCT® was comparable between previously treated pediatric subjects and adult subjects. In some previously untreated patients, a decreased FVIII recovery has been observed in the absence of detectable Factor VIII inhibitors [see Clinical Trial Adverse Reactions/ Previously untreated patients in the ESPEROCT® Product Monograph]. Close monitoring of previously untreated patients including monitoring of the patient's clinical status and post dose FVIII activity is recommended until the incremental recovery is normalized. **Geriatrics** Clinical studies of ESPEROCT® did not include sufficient numbers of subjects age 65 and over to determine whether or not they respond differently than younger subjects. **Pregnant Women** Animal reproduction studies have not been conducted with ESPEROCT®. Given the rare occurrence of hemophilia A in women, experience regarding the use of ESPEROCT® during pregnancy is not available. Therefore, the benefit of using ESPEROCT® during pregnancy must be assessed against the risk for the mother and baby and the product should be used only if clearly needed. **Breast-feeding** Theoretical considerations would indicate that FVIII products could be present in human breast milk, but based on the rare occurrence of hemophilia A in women, experience regarding the use of FVIII products during breastfeeding is not available. Therefore, ESPEROCT® should only be used during breastfeeding if clearly indicated.
CONTRAINDICATIONS	Patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient (including hamster protein), or component of the container. For a complete listing, see Dosage Forms, Strengths, Composition and Packaging in the ESPEROCT® Product Monograph

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STORAGE CONDITIONS & SHELF LIFE	**Prior to Reconstitution** Store refrigerated (2°C – 8°C). Do not freeze. Store in the original package in order to protect from light. ESPEROCT® vials can be stored in the refrigerator (2°C - 8°C) up to the expiration date stated on the label. During the shelf-life, ESPEROCT® may also be stored at room temperature: • up to 30°C for a single period not exceeding 12 months or • up to 40°C for a single period not exceeding 3 months Once the product has been taken out of the refrigerator the product must not be returned to the refrigerator. Record the date when the product was removed from the refrigerator in the space provided on the product carton. Do not use ESPEROCT® after the end of the specified room temperature storage period at up to 30°C or 40°C, or after the expiration date stated on the carton, whichever occurs earlier. **After Reconstitution** Chemical and physical in-use stability have been demonstrated for 24 hours when stored in a refrigerator at 2°C – 8°C, 4 hours when stored at room temperature up to 30°C, and 2 hours when stored between 30°C and 40°C. From a microbiological point of view, the product should be used immediately after reconstitution. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be recommended for longer than as stated above, unless reconstitution has taken place in controlled and validated aseptic conditions. The reconstituted solution should be stored in the vial, with the vial adapter and the syringe still attached. The reconstituted medicinal product should be inspected visually for particulate matter and discolouration prior to administration. The solution should be clear and colourless. Do not use solutions that are cloudy or have deposits.
REFERENCES	ESPEROCT® Product Monograph Date of Initial Approval: July 4, 2019 Date of Revision: May 6, 2020

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