Frequently Asked Questions

Indications and Usage

ESPEROCT® [antihemophilic factor (recombinant), glycopegylated-exei] is indicated for use in adults and children with hemophilia A for on-demand treatment and control of bleeding episodes, perioperative management of bleeding, and routine prophylaxis to reduce the frequency of bleeding episodes

- ESPEROCT® is not indicated for the treatment of von Willebrand disease

Selected Important Safety Information

Contraindications

- Do not use in patients who have known hypersensitivity to Esperoct® or its components, including hamster proteins

Warnings and Precautions

- Hypersensitivity reactions, including anaphylaxis, may occur. Should hypersensitivity reactions occur, discontinue ESPEROCT® and administer appropriate treatment

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Frequently Asked Questions

Q. What is hemophilia?

A. Hemophilia is a hereditary bleeding disorder in which the blood does not clot normally, leading to excessive bleeding. Hemophilia A results from a deficiency in the coagulation factor VIII and hemophilia B results from a deficiency in the coagulation factor IX. Based on the degree of factor deficiency, hemophilia is classified as mild, moderate, or severe. Hemophilia symptoms include increased bruising, bleeding into muscles and joints that may occur without injury, and prolonged bleeding after injury. Hemophilia predominantly affects males, as it is inherited in an X-linked recessive fashion.[1]

Q. What is ESPEROCT®?

A. ESPEROCT® is an injectable medicine used to replace clotting factor VIII that is missing in patients with hemophilia A.[2]

It is a glycopegylated form of recombinant antihemophilic factor; the factor VIII in ESPEROCT® is conjugated to a 40-kDa polyethylene glycol molecule, which increases the half-life and decreases the clearance compared with the nonpegylated molecule.[2]

The FVIII protein in ESPEROCT® is produced in Chinese Hamster Ovary (CHO) cells using recombinant DNA technology. The recombinant factor VIII protein is purified using a series of chromatography steps, one of which is the use of an affinity chromatography, with the use of a monoclonal antibody to selectively isolate the rFVIII from the medium. The production process includes 2 dedicated viral clearance steps: a detergent treatment step for inactivation and a 20-nm filtration step for removal of viruses.[2]

Q. Is ESPEROCT® indicated for prophylactic use?

A. Yes, ESPEROCT® is indicated for use in adults and children with hemophilia A for routine prophylaxis to reduce the frequency of bleeding episodes. Prophylaxis is used in the management of hemophilia to prevent bleeding before it starts.[2]

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Q. What is the mechanism of action of ESPEROCT®?

A. ESPEROCT® is an extended half-life alternative recombinant factor VIII for the treatment of hemophilia A. The recombinant factor VIII in ESPEROCT® is conjugated to a polyethylene glycol molecule, which increases the half-life and decreases the clearance compared with the nonpegylated molecule.[2]

ESPEROCT® works by temporarily replacing the missing factor VIII protein that is needed for effective hemostasis.[2]

Q. Does the polyethylene glycol (PEG) molecule in ESPEROCT® have an effect on its safety profile?

A. No clinically relevant PEG-related or other safety findings have been observed in clinical trials or the toxicology program of ESPEROCT®.[3]

Q. Does ESPEROCT® contain any animal or human components?

A. No additives of human or animal origin are used in the cell culture, purification, and formulation of ESPEROCT®.[2]

Q. When did ESPEROCT® receive FDA approval?

A. ESPEROCT® was approved by the FDA on February 19, 2019.[4]

Q. How is ESPEROCT® supplied?

A. ESPEROCT® is supplied as white to off-white lyophilized powder in single-dose vials, one vial per carton. The diluent for reconstitution of ESPEROCT® is 0.9% saline solution and is supplied in a prefilled diluent syringe.[2]

ESPEROCT® is available in single-dose vials that contain nominally 500, 1000, 1500, 2000, or 3000 IU per vial. The exact IUs are labeled on each package.[2]

Q. How is ESPEROCT® administered?

A. ESPEROCT® is administered by intravenous infusion only.[2]

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Q. What are the inactive ingredients in ESPEROCT®?

A. ESPEROCT® is formulated as a sterile, preservative-free, non-pyrogenic, lyophilized powder for intravenous injection after reconstitution with the provided saline diluent. ESPEROCT® is formulated with the following excipients: sodium chloride, L-histidine, sucrose, polysorbate 80, L-methionine, and calcium chloride.[2]

Q. What are the most frequently reported adverse reactions with ESPEROCT®?

A. The most frequently reported adverse reactions observed in clinical trials (≥1%) were rash, redness, itching (pruritus), and injection site reactions. Additional frequently reported adverse reactions (≥1%) in PUPs included Factor VIII inhibition and hypersensitivity.[2]

Q. Who should not use ESPEROCT®?

A. ESPEROCT® is contraindicated in patients who have known hypersensitivity to ESPEROCT® or its components (including hamster proteins).[2]

Q. Is use of ESPEROCT® associated with the development of inhibitors?

A. Formation of neutralizing antibodies (inhibitors) to factor VIII has occurred following administration of ESPEROCT®. All patients must be monitored for the development of inhibitors by appropriate clinical observation and laboratory testing. If the expected plasma levels of factor VIII activity are not attained, or if bleeding is not controlled with an appropriate dose, testing for factor VIII inhibitors must be performed.[2]

Q. How should ESPEROCT® be stored?

A. ESPEROCT® should be stored in the original package in order to protect it from light. ESPEROCT® should be stored under refrigeration at a temperature of 36°F to 46°F (2°C to 8°C) for up to 30 months from the date of manufacture until the expiration date stated on the carton. During the 30-month shelf life, ESPEROCT® may also be kept at room temperature up to 86°F (≤30°C) for no longer than 12 months or up to 104°F (40°C) for no longer than 3 months.[2]

Clearly record the date when the product was removed from the refrigerator in the space provided on the outer carton. Do not return the product to the refrigerator after room temperature storage. Do not freeze ESPEROCT®. Use ESPEROCT® within 4 hours after reconstitution when stored at <86°F (30°C) or within 24 hours when stored in the refrigerator. Store the reconstituted product in the vial.[2]

Discard any unused reconstituted product.[2]

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Q. Who manufactures ESPEROCT®?

A. ESPEROCT® is manufactured by Novo Nordisk A/S.[2]

Q. Where can I get more information about ESPEROCT®?

A. If you would like additional information about ESPEROCT®, please visit https://www.novomedlink.com/rare-bleeding-disorders/products/treatments/esperoct.html.

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Important Safety Information

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Warnings and Precautions

- Hypersensitivity reactions, including anaphylaxis, may occur. Should hypersensitivity reactions occur, discontinue ESPEROCT® and administer appropriate treatment
- Development of neutralizing antibodies (inhibitors) has occurred. Perform an assay that measures Factor VIII inhibitor concentration if bleeding is not controlled with the recommended dose of ESPEROCT® or if the expected plasma Factor VIII activity levels are not attained
- Temporary decrease in Factor VIII incremental recovery (IR) has been observed after ESPEROCT® infusion, within the first 5 exposure days, in previously untreated patients (PUPs) <6 years of age. During the decreased IR period, these subjects may have an increased bleeding tendency. If bleeding is not controlled with the recommended dose of ESPEROCT® and/or the expected Factor VIII activity levels are not attained and Factor VIII inhibitors are not detected, consider adjusting the dose, dosing frequency, or discontinuing ESPEROCT®

Adverse Reactions

- The most frequently reported adverse reactions in clinical trials (≥1%) were rash, redness, itching (pruritus), and injection site reactions. Additional frequently reported adverse reactions (≥1%) in PUPs included Factor VIII inhibition and hypersensitivity

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References:
1. Srivastava A, Santagostino E, Dougall A, et al; WFH Guidelines for the Management of Hemophilia panelists and co-authors. WFH Guidelines for the Management of Hemophilia, 3rd edition. *Haemophilia.* 2020;26(suppl 6):1-158. **2.** Esperoct® [package insert]. Plainsboro, NJ: Novo Nordisk Inc. **3.** Tiede A, Brand B, Fischer R, et al. Enhancing the pharmacokinetic properties of recombinant factor VIII: first-in-human trial of glycoPEGylated recombinant factor VIII in patients with hemophilia *A. J Thromb Haemost.* 2013;11(4):670-678. **4.** US Food and Drug Administration. BLA Approval letter [BL125671/0]. Published February 19, 2019. Accessed March 11, 2024. https://fda.report/media/120350/February+19%2C+2019+Approval+Letter+-+ESPEROCT.pdf.

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