






ESPEROCT® Antihemophilic Factor (Recombinant), Glycopegylated-exei

Trade Unit Product Information

Brand Name	ESPEROCT® 500 IU	ESPEROCT® 1000 IU	ESPEROCT® 1500 IU	ESPEROCT® 2000 IU	ESPEROCT® 3000 IU
Generic Name	Antihemophilic Factor (Recombinant), Glycopegylated-exei	Antihemophilic Factor (Recombinant), Glycopegylated-exei	Antihemophilic Factor (Recombinant), Glycopegylated-exei	Antihemophilic Factor (Recombinant), Glycopegylated-exei	Antihemophilic Factor (Recombinant), Glycopegylated-exei
WAC Price (per IU)	\$2.55	\$2.55	\$2.55	\$2.55	\$2.55
Expiration Date	30 months dating from manufactured date	30 months dating from manufactured date	30 months dating from manufactured date	30 months dating from manufactured date	30 months dating from manufactured date
Package Presentation	1 carton containing: ESPEROCT® in single-dose vial, syringe pre-filled with 4 mL saline diluent, vial adapter	1 carton containing: ESPEROCT® in single-dose vial, syringe pre-filled with 4 mL saline diluent, vial adapter	1 carton containing: ESPEROCT® in single-dose vial, syringe pre-filled with 4 mL saline diluent, vial adapter	1 carton containing: ESPEROCT® in single-dose vial, syringe pre-filled with 4 mL saline diluent, vial adapter	1 carton containing: ESPEROCT® in single-dose vial, syringe pre-filled with 4 mL saline diluent, vial adapter
NDC/List Number	0169 8500 01	0169 8100 01	0169 8150 01	0169 8200 01	0169 8300 01
UPC	3 0169 850001 9	3 0169 810001 1	3 0169 815001 6	3 0169 820001 8	3 0169 830001 5
Bar Code					
Trade Unit Dimensions (inches L X W X H)	4.094 X 2.539 X 1.752	4.094 X 2.539 X 1.752	4.094 X 2.539 X 1.752	4.094 X 2.539 X 1.752	4.094 X 2.539 X 1.752
Trade Unit Weight (ounces)	1.587	1.587	1.587	1.587	1.587
Storage (Storing ESPEROCT® at room temperature [up to 86°F] will reduce expiration date to 12 months. Storing ESPEROCT® up to 104°F will reduce expiration date to 3 months.)	Keep refrigerated 36°F-46°F (2°C-8°C) up to 30 months or expiration date	Keep refrigerated 36°F-46°F (2°C-8°C) up to 30 months or expiration date	Keep refrigerated 36°F-46°F (2°C-8°C) up to 30 months or expiration date	Keep refrigerated 36°F-46°F (2°C-8°C) up to 30 months or expiration date	Keep refrigerated 36°F-46°F (2°C-8°C) up to 30 months or expiration date

Important codes for ESPEROCT®

Product J-Code	J-7204
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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

Important Safety Information

Contraindications

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




Please see additional Important Safety Information on next page.
Please [click here](#) for Prescribing Information.

esperoctr®
antihemophilic factor
(recombinant),
glycopegylated-exei

Administration Kit



Product Name	Administration Set (Free of charge. Limited quantities available.)
List Number	720006
NDC/List Number	0169-7200-06
UPC	3 0169 720006 4
Bar Code	 3 01697 20006 4
Trade Unit Dimensions (inches L X W X H)	4.125 X 2.625 X 1.5
Trade Unit Weight	0.8 oz
Contents	1 winged needle infusion set (25 gauge, DEHP free) 2 adhesive bandages 2 gauze pads 2 alcohol swabs 1 instructions for use

Important Safety Information (cont'd)

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. Additional frequently reported adverse reactions (≥1%) in PUPs included Factor VIII inhibition and hypersensitivity

Reference: 2022 Part A MAC Update. Centers for Medicare & Medicaid Services. Updated September 6, 2023. Accessed March 12, 2024. <https://www.cms.gov/medicare/coding-billing/skilled-nursing-facility-snf-consolidated-billing/2022-part-a-mac-update>

**Please see additional Important Safety Information on page 1.
Please [click here](#) for Prescribing Information.**

To order, call: **1-844-30-EIGHT** (1-844-303-4448)



Novo Nordisk Inc., 800 Scudders Mill Road, Plainsboro, New Jersey 08536 U.S.A.

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