# Frequently Asked Questions

## Indications and Usage

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

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

## Important Safety Information

**Contraindications**

- Do not use in patients who have had life-threatening hypersensitivity reactions, including anaphylaxis, to Novoeight® or its components, including hamster proteins

**Warnings and Precautions**

- Anaphylaxis and severe hypersensitivity reactions are possible. Patients may develop hypersensitivity to hamster proteins, which are present in trace amounts in the product. Should symptoms occur, discontinue Novoeight® and administer appropriate treatment

# Frequently Asked Questions

## Q. What is hemophilia?

**A.** Hemophilia is a hereditary disorder that prevents blood from clotting normally, resulting in excessive bleeding. It is the result of a deficiency of 1 of 2 coagulation factors. Deficiency of factor VIII leads to hemophilia A and deficiency of factor IX leads to hemophilia B. Hemophilia is classified as mild, moderate, or severe based on the degree of factor deficiency. Symptoms of hemophilia include increased bruising, bleeding into muscles and joints even in the absence of injury, and prolonged bleeding after injury. Hemophilia is seen predominantly in males as it is inherited in an X-linked recessive fashion.[1]

## Q. What is Novoeight®?

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

Novoeight® is a specialty pharmaceutical product that is synthesized using a genetically engineered Chinese hamster ovary (CHO) cell line that secretes recombinant factor VIII (rFVIII) into the cell culture medium. The rFVIII protein is purified using a series of chromatography steps, one of which is the use of an immunoaffinity column in which a monoclonal antibody, produced in CHO cells and directed against factor VIII, is employed 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 Novoeight® indicated for prophylactic use?

**A.** Yes, Novoeight® 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]

## Q. How is Novoeight® different than other factor VIII products?

**A.** Novoeight® is a third-generation, standard half-life, B-domain truncated, recombinant factor VIII product for the treatment of hemophilia A. It is designed to offer reliability, safety, and portability for people with hemophilia A. Novoeight® is purified using a 5-step process, including immunoaffinity chromatography, anionic exchange chromatography, gel filtration, and 2 viral clearance steps. Novoeight® can be stored at up to 104°F (40°C) for up to 3 months or up to 86°F (30°C) for up to 12 months. It has stability after reconstitution up to 2 hours at up to 104°F and up to 4 hours at up to 86°F.[2,3]



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novoeight®
*Antihemophilic Factor (Recombinant)*

## Q. How is Novoeight® obtained?

**A.** Novoeight® can be accessed and acquired through specialty pharmacy distributors, hemophilia home care agencies, and hemophilia treatment center 340B programs.

## Q. What is the mechanism of action of Novoeight®?

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

## Q. Does Novoeight® contain any animal or human components?

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

## Q. When did Novoeight® receive FDA approval?

**A.** Novoeight® was FDA approved on October 15, 2013.[4]

## Q. How is Novoeight® supplied?

**A.** Novoeight® is supplied as white, lyophilized powder in single-dose vials, one vial per carton. The diluent for reconstitution of Novoeight® is 0.9% sodium chloride solution and is supplied as a clear, colorless solution in a prefilled diluent syringe.[2]

Novoeight® is available in **single-dose** vials that contain nominally 250, 500, 1000, 1500, 2000, or 3000 international units (IU) per vial.[2] The exact IUs are labeled on each package.

## Q. How is Novoeight® administered?

**A.** Novoeight® is administered by intravenous injection only.[2]



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## Q. Who can administer Novoeight®?

**A.** Novoeight® is administered by intravenous injection. Patients may infuse Novoeight® at a hemophilia treatment center, at a health care provider's office, or at home. Patients should be trained to infuse by their health care provider prior to self-infusing.[2]

## Q. What are the inactive ingredients in Novoeight®?

**A.** Novoeight® is formulated as a sterile, non-pyrogenic, lyophilized powder for intravenous injection after reconstitution with the diluent (0.9% sodium chloride). When reconstituted with the appropriate volume of diluent, the product contains the following components per mL: 18 mg sodium chloride, 1.5 mg L-histidine, 3 mg sucrose, 0.1 mg polysorbate 80, 0.055 mg L-methionine, and 0.25 mg calcium chloride dihydrate. The product contains no preservative.[2]

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

**A.** The most frequently reported adverse reactions observed in clinical trials (≥1%) were inhibitors in Previously Untreated Patients (PUPs), injection site reactions, and pyrexia.[2]

## Q. Who should not use Novoeight®?

**A.** Novoeight® is contraindicated for use in patients who have had life-threatening hypersensitivity reactions, including anaphylaxis, to Novoeight® or its components (including traces of hamster proteins).[2]

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

**A.** Formation of neutralizing antibodies (inhibitors) to factor VIII can occur following administration of Novoeight®. Previously untreated patients (PUPs) are at greatest risk for inhibitor development with all factor VIII products. Inhibitors have been reported following administration of Novoeight® in PUPs. 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]

In the completed main phase of the clinical trial in PUPs, 24 of 56 (42.9%) patients developed inhibitors with a mean of 14.1 exposure days at the time of the first positive inhibitor test; 15 (26.8%) PUPs developed high-titer (≥ 5 BU) inhibitors.[2] The inhibitor rate observed in PUPs is

consistent with results observed in the SIPPET study and in patients at mutational risk of developing inhibitors. Overall, there is a favorable benefit-risk assessment for use of Novoeight® in all studied populations in the currently approved indications.[5]

In one of the largest clinical trials of rFVIII to date, there were no cases of confirmed inhibitors to factor VIII in 242 previously treated patients who were switched to Novoeight®.[2] These PTPs received at least one dose of Novoeight® during the clinical evaluation of Novoeight® with more than 140,000 exposure days (corresponding to over 900 patient years).[2]

## Q. How should Novoeight® be stored?

**A.** Novoeight® should be stored in the original package in order to protect it from light. Novoeight® 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, Novoeight® 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. Do not freeze Novoeight®. Use Novoeight® within 4 hours after reconstitution when stored at <86°F (30°C) or within 2 hours when stored between 86°F (30°C) to 104°F (40°C). Store the reconstituted product in the vial.[2]

Discard any unused reconstituted product.[2]

## Q. Who manufactures Novoeight®?

**A.** Novoeight® is manufactured by Novo Nordisk A/S. Novoeight® is distributed by Novo Nordisk Inc.[2]

## Q. Where can I get more information about Novoeight®?

**A.** If you would like additional information about Novoeight®, please call Novo Nordisk Inc. at 1-844-30-EIGHT.[2]



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**Warnings and Precautions**

- Anaphylaxis and severe hypersensitivity reactions are possible. Patients may develop hypersensitivity to hamster proteins, which are present in trace amounts in the product. Should symptoms occur, discontinue Novoeight® and administer appropriate treatment
- Development of activity-neutralizing antibodies (inhibitors) may occur. Previously untreated patients (PUPs) are at greatest risk for inhibitor development with all factor VIII products. Inhibitors have been reported following administration of Novoeight® in PUPs. If expected plasma factor VIII activity levels are not attained, or if bleeding is not controlled with an appropriate dose, perform testing for factor VIII inhibitors

**Adverse Reactions**

- The most frequently reported adverse reactions (≥1%) were inhibitors in Previously Untreated Patients (PUPs), injection site reactions, and pyrexia.



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**References:**

**1.** Srivastava A, Santagostino E, Dougall A, et al. WFH Guidelines for the Management of Hemophilia, 3rd edition. *Haemophilia.* 2020;26(suppl 6):1-158.doi:10.1111/hae.14046 **2.** Novoeight® [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; 2020. **3.** Wang W, Wang YJ, Kelner DN. Coagulation factor VIII: structure and stability. *Int J Pharm.* 2003; 259(1-2):1-15. **4.** U.S. Food and Drug Administration, Office of Blood Research and Review, Center for Biologics Evaluation and Research. Novoeight® approval letter, October 15, 2013. Accessed November 15, 2022. http://wayback.archive-it.org/7993/20170723023536/https://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/ucm371095.htm. **5.** U.S. Food and Drug Administration. Novoeight® Summary Basis for Regulatory Action letter, November 30, 2018. Accessed November 15, 2022. https://www.fda.gov/media/119122/download.

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