







Novoeight® Antihemophilic Factor (Recombinant)



Each vial comes with a syringe appropriately pre-filled with diluent.

Trade Unit Product Information

Brand Name	Novoeight® 250 IU	Novoeight® 500 IU	Novoeight® 1000 IU	Novoeight® 1500 IU	Novoeight® 2000 IU	Novoeight® 3000 IU
Generic Name	Antihemophilic Factor (Recombinant)	Antihemophilic Factor (Recombinant)	Antihemophilic Factor (Recombinant)	Antihemophilic Factor (Recombinant)	Antihemophilic Factor (Recombinant)	Antihemophilic Factor (Recombinant)
WAC Price (per IU)	\$2.07	\$2.07	\$2.07	\$2.07	\$2.07	\$2.07
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	30 months dating from manufactured date
Package Presentation	1 carton containing: Novoeight® in single-dose vial, syringe pre-filled with 4 mL sodium chloride diluent, vial adapter	1 carton containing: Novoeight® in single-dose vial, syringe pre-filled with 4 mL sodium chloride diluent, vial adapter	1 carton containing: Novoeight® in single-dose vial, syringe pre-filled with 4 mL sodium chloride diluent, vial adapter	1 carton containing: Novoeight® in single-dose vial, syringe pre-filled with 4 mL sodium chloride diluent, vial adapter	1 carton containing: Novoeight® in single-dose vial, syringe pre-filled with 4 mL sodium chloride diluent, vial adapter	1 carton containing: Novoeight® in single-dose vial, syringe pre-filled with 4 mL sodium chloride diluent, vial adapter
NDC/List Number	0169-7825-01	0169-7850-01	0169-7810-01	0169-7815-01	0169-7820-01	0169-7830-01
UPC	3 0169 782501 4	3 0169 785001 6	3 0169 781001 0	3 0169 781501 5	3 0169 782001 9	3 0169 783001 8
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	4.094 X 2.539 X 1.752
Trade Unit Weight (ounces)	1.587	1.587	1.587	1.587	1.587	1.587
Storage (Storing Novoeight® at room temperature [up to 86°F] will reduce expiration date to 12 months. Storing Novoeight® 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	Keep refrigerated 36°F-46°F (2°C-8°C) up to 30 months or expiration date

Important Codes for Novoeight®

Product J-Code	J7182 ¹
Congenital FVIII disorder	ICD-9: 286 ² ICD-10: D66 ³

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




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

novoeight®
Antihemophilic Factor
(Recombinant)

Administration Kit



Product Name	Novoeight® Administration Kit (Free of charge. Limited quantities available.)
List Number	720006
NDC/List Number	0169-7200-06
UPC	3 01697 20006 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

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

Important Safety Information (cont'd)

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 ($\geq 1\%$) were inhibitors in Previously Untreated Patients (PUPs), injection site reactions, and pyrexia.

References: **1.** Centers for Medicare & Medicaid Services. 2019 HCPCS alpha-numeric index. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Downloads/2019-HCPCS-Index.pdf>. Accessed April 29, 2020. **2.** Centers for Disease Control and Prevention. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM). ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD9-CM/2011/. Updated September 8, 2011. Accessed April 29, 2020. **3.** Centers for Disease Control and Prevention. International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM). ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2019/. Updated April 12, 2019. Accessed April 29, 2020.

Please see additional Important Safety Information on previous page.
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