8-9064-07-301-3_V1-5.indd 1
16-09-2020 09:16:11

Regulatory Operations
Carton: 2010-22-001-26-314
Current 2

EMA

Lacquerform 30323-1 Lacquer free area:

Colour: PMS 280C + Cyan
+ PMS 375C + Black + PMS Warm Red C

Braille No.: XXXX-XX-X
Placement: Panel 1 (Front)

**NovoEight®** 500 IU

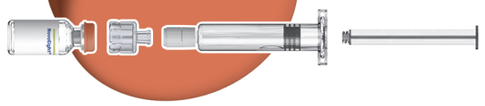
Powder and solvent for solution for injection

**turoctocog alfa**

(human coagulation factor VIII (rDNA))

**Intravenous use**

MAL16085029AZ



One ml of NovoEight® contains approximately 125 IU of human coagulation factor VIII (rDNA), turoctocog alfa after reconstitution
**Powder:** Sodium chloride, L-histidine, sucrose, polysorbate 80, L-methionine, calcium chloride dihydrate, sodium hydroxide, hydrochloric acid
**Solvent:** Sodium chloride, water for injections
**Pack contains:** 1 powder vial, 4 ml solvent in prefilled syringe, plunger rod and vial adapter

Jauhi ubat dari kanak-kanak
This is a STERILE product
Controlled Medicine

Manuf./Expiry/Batch:



**NovoEight®** 500 IU

Powder and solvent for solution for injection

**turoctocog alfa**

(human coagulation factor VIII (rDNA))

Read the package leaflet before use
Keep out of the sight and reach of children
**Store in a refrigerator. Do not freeze**
During storage, the product may be kept at:
- room temperature (≤ 30°C) for a single period no longer than 9 months

**or**
- above room temperature (30°C up to 40°C) for a single period no longer than 3 months

Taken out of refrigerator:_____Stored at ≤ 30°C __ Stored at 30°C up to 40°C __
Store in the original package in order to protect it from light

**Manufactured by:**
Novo Nordisk A/S
Hagedornsvej 1
DK-2820 Gentofte
Denmark

**Released by:**
Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd
Denmark

**Product Registration Holder:**
Novo Nordisk Pharma (M) Sdn Bhd
Menara 1 Sentrum, Level 16
No. 201, Jalan Tun Sambanthan
50470 Kuala Lumpur

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