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16-09-2020 11:34:15

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 Green C

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

Intravenous use
MAL16085030AZ

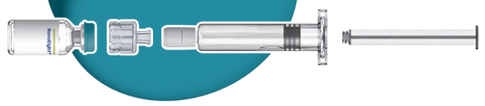
novo nordisk®

NovoEight® **1000 IU**

Powder and solvent
for solution for injection

turoctocog alfa

(human coagulation factor VIII (rDNA))



Intravenous use
MAL16085030AZ

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Powder and solvent for solution for injection

turoctocog alfa

(human coagulation factor VIII (rDNA))

One ml of NovoEight® contains approximately 250 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® **1000 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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