

22-001-26

8-9064-07-301-3

NovoEight®

500 IU

Powder and solvent
for solution for injection

turoctocog alfa
(human coagulation
factor VIII (rDNA))

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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
Høllas Alle
DK-4400 Kalundborg
Denmark
© 2019

Released by:
Novo Nordisk A/S
Novo Alle
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

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

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Intravenous use

MAL16085029AZ

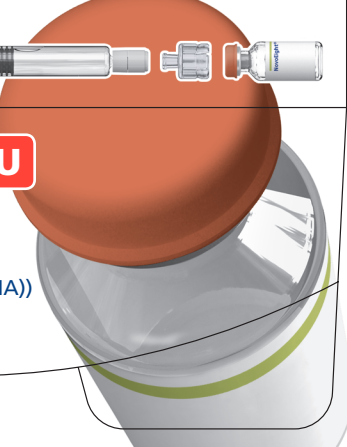
 

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Regulatory Operations
Carton: 2010-22-001-26-314
Current 2
Lacquerform 30323-1

EMA

Lacquer free area:

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

16-09-2020 09:16:11

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