NovoEight® prefilled syringe 4-steps reconstitution

1 Prepare the vial and syringe

Take the vial, the vial adapter and the prefilled syringe out of the carton. Leave the plunger rod untouched in the carton.

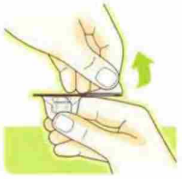
Bring the vial and the prefilled syringe to room temperature. You can do this by holding them in your hands until they feel as warm as your hands.

⚠ **Do not use any other way to heat the vial and prefilled syringe.**

Remove the plastic cap from the vial. If the plastic cap is loose or missing, do not use the vial.

Wipe the rubber stopper on the vial with a sterile alcohol swab and allow it to air dry for a few seconds before use.

2 Place the vial adapter onto the vial



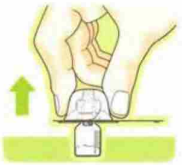
Remove the protective paper from the vial adapter.

If the protective paper is not fully sealed or if it is broken, do not use the vial adapter.

⚠ **Do not take the vial adapter out of the protective cap with your fingers.**

Turn over the protective cap and snap the vial adapter onto the vial.

⚠ **Once attached do not remove the vial adapter from the vial.**

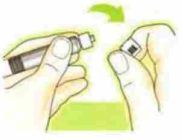


Lightly squeeze the protective cap with your thumb and index finger as shown.

Remove the protective cap from the vial adapter.

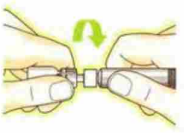
3 Connect the plunger rod to the syringe

Grasp the plunger rod by the wide top and immediately connect the plunger rod to the syringe by turning it clockwise into the plunger inside the prefilled syringe until resistance is felt.



Remove the syringe cap from the prefilled syringe by bending it down until the perforation breaks.

⚠ **Do not touch the syringe tip under the syringe cap.**



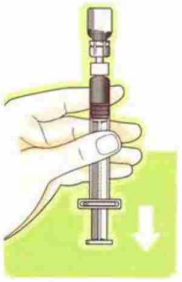
Screw the prefilled syringe securely onto the vial adapter until resistance is felt.

4 Dissolve the powder with the solvent

Hold the prefilled syringe slightly tilted with the vial pointing downwards. Push the plunger rod to inject all the solvent into the vial.

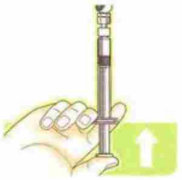
Keep the plunger rod pressed down and swirl the vial gently until all the powder is dissolved.

⚠ **Do not shake the vial as this will cause foaming.**



Keep the plunger rod pushed completely in. Turn the syringe with the vial upside down. Stop pushing the plunger rod and let it move back on its own while the reconstituted solution fills the syringe. Pull the plunger rod slightly downwards to draw the reconstituted solution into the syringe.

In case you only need part of the entire vial, use the scale on the syringe to see how much reconstituted solution you withdraw, as instructed.



While holding the vial upside down, tap the syringe gently to let any air bubbles rise to the top. Push the plunger rod slowly until all air bubbles are gone.

Unscrew the vial adapter with the vial.

NovoEight® is now ready for use

It is recommended to use NovoEight® immediately after reconstitution.

If not used immediately, in-use storage times and conditions prior to use are the responsibility of the users and would normally not be longer than 4 hours stored at ≤30°C or 24 hours at 2°C - 8°C.

If a larger dose is needed, repeat steps with additional vials, vial adapters and prefilled syringes.

Key information for patients who have been prescribed NovoEight®▼(turoctocog alfa)

NovoEight® is a recombinant factor VIII product used to treat and prevent bleeding episodes in patients with haemophilia A (congenital factor VIII deficiency)

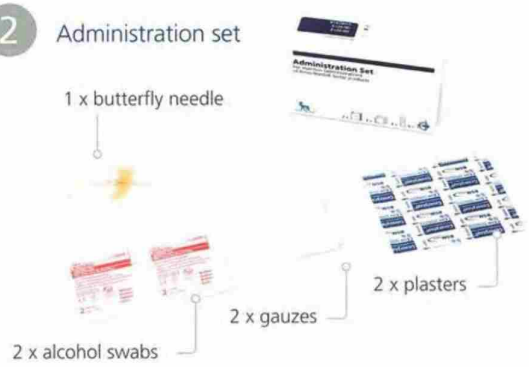
Your healthcare professional will explain and demonstrate how you should administer your NovoEight®

For more information on molecular characteristics and purity of NovoEight® please ask your healthcare professional

Compact Packaging

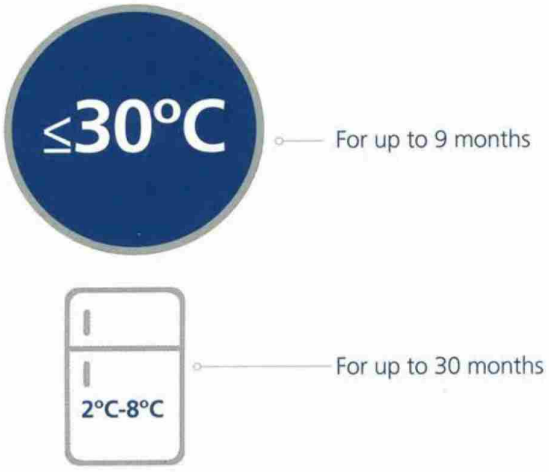
1 NovoEight® with pre-filled syringe

2 Administration set



General Storage Information

Before opening, NovoEight® can be stored at:



- Once the product has been taken out of the refrigerator it must not be returned into the refrigerator
- Record the date when the product was taken out of the refrigerator carton

After reconstitution, NovoEight® can be stored at:

* After reconstitution, chemical and physical in-use stability has been demonstrated for 4 h stored at up to 30°C.
† After reconstitution, chemical and physical in-use stability has been demonstrated for 24 h stored at 2°C–8°C.

- Reconstitution instructions overleaf
- Always read the full instructions within the package insert
- Do not use NovoEight® after the expiry date printed on the carton. The expiry date refers to the last day of the month

UK only
Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novo Nordisk Limited (Telephone Novo Nordisk Customer Care Centre 0845 6005055). Calls may be monitored for training purposes.

Ireland only
Adverse events should be reported. Information about adverse event reporting is available at www.hpra.ie. Adverse events should also be reported to the Novo Nordisk Medical department; Tel: 1850 665 665

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information

novo nordisk®

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