Your guide to reconstituting and administering ADVATE (octocog alfa [recombinant human coagulation factor VIII])

This guide has been developed by Takeda and is intended only for patients who have been prescribed ADVATE.

This guide is not a substitute for the Patient Information Leaflet included in your pack. Please read the Patient Information Leaflet carefully.

Prepare for your injection:

- Aseptic technique is required during preparation of the solution and administration
- Do not use after the expiry date stated on the labels and carton
- Do not use if the BAXJECT II device, its sterile barrier system or its packaging is damaged or shows any sign of deterioration as indicated by the symbol

- **Do not refrigerate** the solution after preparation
- If the product is still stored in a refrigerator, take both the ADVATE powder and solvent vials from the refrigerator and let them reach room temperature (between 15°C and 25°C)
- Wash your hands thoroughly using soap and warm water
- Remove caps from powder and solvent vials
- Cleanse stoppers with alcohol swabs

- Place vials on a flat clean surface
- Use only the sterilised water for injections and the reconstitution device for preparation of the solution that are provided with each package of ADVATE. ADVATE must not be mixed with other medicinal products or solvents
- **Do not try to administer the injection unless you have received special training from your doctor or nurse**

CONNECT WATER VIAL

1. **Open the package of BAXJECT II** device by peeling away the paper lid without touching the inside
2. **Do not remove the device from the package**

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3. **Turn** the package over and **insert the clear plastic spike through the solvent stopper**

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ADVATE Vial   Water Vial
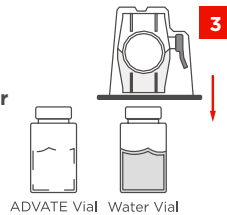
4. **Grip** the package at its edge and pull the package off BAXJECT II
5. **Do not remove the blue cap from the BAXJECT II device**

4
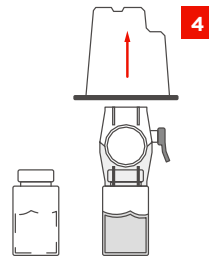
CONNECT ADVATE VIAL

6. With BAXJECT II attached to the solvent vial, **invert** the system so that the solvent vial is on top of the device
7. **Insert** the white plastic spike through the ADVATE powder stopper. The vacuum will draw the solvent into the ADVATE powder vial

7
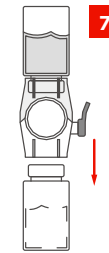
8. **Swirl** gently until all ADVATE is dissolved
9. **Be sure** that the ADVATE powder is completely dissolved, otherwise not all reconstituted solution will pass through the device filter. ADVATE dissolves rapidly (usually in less than 1 minute). After reconstitution the solution should be clear, colourless and free from foreign particles
10. Inspect the solution for particulate matter and discolouration prior to administration (it should be clear, colourless and free from foreign particles). **Do not use** if the solution is not fully clear or not completely dissolved

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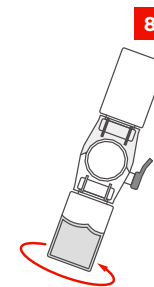
11. **Remove** the blue cap from BAXJECT II
12. **Do not draw air into the luer lock syringe**
13. **Connect** the syringe to BAXJECT II

13
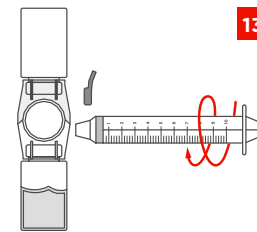
WITHDRAW MIXED ADVATE

14. **Invert** the system (the vial with the reconstituted solution has to be on top)
15. **Draw** the reconstituted solution into the syringe by pulling the plunger back slowly
16. **Disconnect** the syringe
17. **Attach** a butterfly needle to the syringe and inject the reconstituted solution into a vein. The solution should be administered slowly, at a rate that you are comfortable with. Do not exceed 10 ml per minute
18. **Discard** any unused solution appropriately

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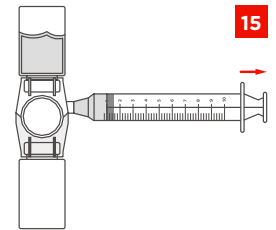
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the national reporting system: Yellow Card Scheme www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

The information provided is not a substitute for professional and/or medical advice. Please consult a healthcare professional or your haemophilia treatment centre for further advice.

It is strongly recommended that every time you administer ADVATE, the name and batch number of the product are recorded.

If you are having any difficulties reconstituting ADVATE, please contact your haemophilia team in the first instance. Alternatively, contact us at Takeda: e-mail: medinfoemea@takeda.com or telephone: +44 (0)3333 000 181.