BAXJECT II Hi-Flow
Needleless Transfer Device

RECONSTITUTION AS EASY AS 1-2-3

A detailed guide to reconstituting FEIBA-NF therapy

FEIBA
Factor VIII Inhibitor Bypassing Fraction

BEFORE YOU BEGIN

To be used with FEIBA-NF only

- Bring vials to room temperature
- Wash hands
- Remove caps from vials
- Wipe vial tops with alcohol swabs and let dry

PURPLE = FEIBA-NF vial -connect to powder vial

CLEAR = Water vial -connect to water vial

Plastic spike

1 CONNECTING Water vial

A

- **Remove** lid from package without touching the device

Do not remove device from package.

B

- **Place** vials on hard flat surface
- **Connect** clear side of device to water vial
- **Press down** until clear spike pierces water vial stopper

C

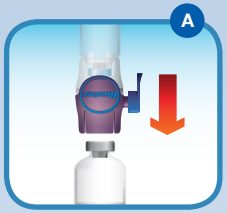
- **GRIP** packaging at edge and lift it off, leaving device connected to water vial

Do not remove blue cap. Do not touch purple spike.

2 CONNECT Powder vial

A

- **Turn** device over and connect purple side of device to FEIBA-NF vial
- Press down until purple spike pierces vial stopper



B

- **Wait** for water to enter product vial
- **Swirl** gently to dissolve FEIBA-NF

C

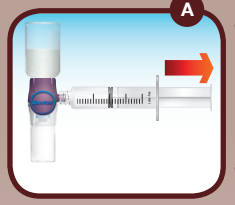
- **Remove** blue cap from device and attach syringe

Do not inject air.

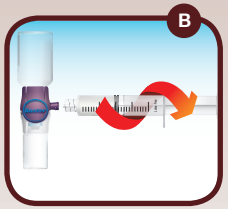
3 WITHDRAW dissolved FEIBA-NF solution

A

- **Turn** device over so empty water vial is at the bottom
- SLOWLY **pull** back on syringe plunger to withdraw FEIBA-NF solution



If you find it impossible to withdraw some or all of the mixed product into the syringe, there may be air in the device. Please refer to Troubleshooting Information on the reverse side of this guide.



B

- **Disconnect** syringe with reconstituted solution

It is acceptable for a small amount of water or foam to be left behind. If the water does not transfer successfully, please refer to Troubleshooting Information on the reverse side of this guide.

HOW TO MIX MORE THAN ONE VIAL WITH A LARGE SYRINGE

- Mix all product vials, using a new **BAXJECT II Hi-Flow** device for each vial, as directed in Step 1 and Step 2
- Follow Step 3 to draw the product from each vial into the large syringe
- The **BAXJECT II Hi-Flow** device is intended for use with a single vial of FEIBA-NF and is for single use only. Dispose of the **BAXJECT II Hi-Flow** device as directed by your Haemophilia Treatment Centre

HANDY HINTS

- When withdrawing solution for infusion: the purple side of the **BAXJECT II Hi-Flow** device will be on top and the word 'Baxalta" will be the right way up.

  When withdrawing solution, the liquid should always be in the top vial.
- *Your syringe is used to provide pressure, either to withdraw solution or to inject air. See the Troubleshooting section for further details.*

Baxalta

BAXJECT II Hi-Flow
Needleless Transfer Device

TROUBLESHOOTING GUIDE

FEIBA
Factor VIII Inhibitor Bypassing Fraction

Scenario 1: If water does not transfer successfully

1A: If water does not transfer successfully

1B: Ensure water vial is connected correctly. Turn device over so FEIBA-NF vial is at the bottom. Attach syringe

1C: Pull plunger back to withdraw air until all water has transferred

1D: Remove syringe and push plunger in

1E: Reconnect syringe and swirl gently to mix FEIBA-NF solution. Turn vials over

1F: Slowly pull back on syringe plunger to withdraw FEIBA-NF solution

1G: Remove syringe

If troubleshooting scenarios 1, 2 or 3 fail to address the problems you are having, please contact your local Haemophilia Treatment Centre

Scenario 2: If water vial is incorrectly connected to purple side of device

2A: If water vial is incorrectly connected to purple side of device

2B: With water vial at the bottom, attach syringe and pull plunger back to withdraw air

2C: Turn device over and slowly press plunger until water has transformed

2D: Swirl gently to mix FEIBA-NF solution

2E: Turn device over and pull plunger back until all dissolved FEIBA-NF is in the bottom vial

2F: Remove syringe and push plunger in

2G: Re-attach syringe and turn device over

2H: Slowly pull back on syringe plunger to withdraw FEIBA-NF reconstituted solution

2I: Remove syringe

Scenario 3: If dissolved FEIBA-NF has leaked into water vial or air has been injected

3A: i.e. dissolved FEIBA-NF has leaked into water vial or air has been injected

3B: Turn device over so FEIBA-NF vial is at the bottom then follow 1C, 1D, 1E, 1F of troubleshooting scenario

Baxalta

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BEFORE PRESCRIBING PLEASE REVIEW PRODUCT INFORMATION AVAILABLE FROM BAXALTA BY CALLING 1800 812 734

PBS Information: This product is not listed on the PBS.
Please refer to the National Blood Authority for details.

MINIMUM PRODUCT INFORMATION FEIBA-NF (Factor VIII inhibitor bypassing fraction). **Indications:** FEIBA-NF is indicated for routine prophylaxis, control of spontaneous bleeding episodes and use in surgery in haemophilia A or B patients with inhibitors. **Contra-indications:** Patients with a normal coagulation mechanism, or significant signs of disseminated intravascular coagulation (DIC) or fibrinolysis. Cardiac surgery involving cardiopulmonary bypass and procedures involving extracorporeal membrane oxygenation (ECMO) due to the high risk of thrombotic adverse events. In patients with coronary heart disease or acute thrombosis and/or embolism the use of FEIBA-NF is only indicated in life threatening bleeding events. **Precautions:** FEIBA-NF has been associated with severe allergic and anaphylactoid reactions, and serious thrombotic events. The risk of thrombotic and thromboembolic events may be increased with high doses. Use with caution in subjects with pre-existing risk factors for thrombosis. Monitor for development of DIC, acute coronary ischemia, and signs/symptoms of other thrombotic or thromboembolic events. FEIBA-NF is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses and theoretically Creutzfeldt-Jacob Disease (CJD) agents that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors and by dedicated virus removal and inactivation procedures included in the manufacturing process. Despite these measures, the possibility of transmitting infective agents cannot be totally excluded. Vaccination should be considered where appropriate. Single doses of 100 U/kg body weight (bw) and daily doses of 200 U/kg bw should not be exceeded. See full Product Information (PI). **Interactions:** The use of anti-fibrinolytic agents in combination with FEIBA-NF is not recommended. If treatment with both agents are indicated, administer at least 12 hours apart. **Adverse Reactions (AR):** Common ARs from clinical trials include hypersensitivity reactions, dizziness, headache, rash and hepatitis B surface antigen positive. Post-marketing ARs include DIC, anaphylactic and hypersensitivity reactions, myocardial infarction, arterial and venous thrombosis, hypotension, and pulmonary embolus. Refer to full PI for all ARs. **Dosage and Administration:** For intravenous infusion. As a general rule a dose of 50 - 100 units of FEIBA-NF per kg bw is recommended. The daily dose should not exceed 200 U/kg bw. Do not exceed an infusion rate of 2 units FEIBA-NF per kg bw per minute. For spontaneous haemorrhage: see full PI for dosing. For surgery: 50-100 U/kg bw at intervals up to 6 hours. Routine prophylaxis: For prevention of bleeding, dose 85 ± 15 units per kg bw (70 - 100 U/kg bw) every other day (3-4 times weekly). Adjust based on clinical response. For all dosing, reconstitution, and administration details see PI. Based on FEIBA-NF approved Product Information amended 21 May 2014.