Takeda Canada Inc.
Bay Adelaide Centre
22 Adelaide Street West, Suite 3800
Toronto, ON M5H 4E3

August 15, 2023

Replacement BAXJECT II Hi-Flow Reconstitution Devices co-packaged with FEIBA NF

Marketing Authorization Number(s):

FEIBA NF:

Strength	DIN	Drug Product Lot #	Labelled BJ II HF Device Lot #'s
2500 IU	02353903	F2W053AE	GR349772
2500 IU	02353903	F2W053AF	GR349772

Dear Healthcare professional,

Takeda would like to inform you of the following:

Summary

- **Takeda has decided to voluntarily replace BAXJECT II Hi-Flow reconstitution devices produced by Takeda's contract device manufacturer between October 2021 and January 2022, co-packaged for use in conjunction with FEIBA NF.**
- **Takeda will provide replacement BAXJECT II Hi-Flow reconstitution devices to those Healthcare Professionals who have received the impacted batches listed above.**
- **If you require replacement devices, please contact Canada Medical Information at Takeda at 1-800-268-2772 or medinfoCA@takeda.com.**
- **BAXJECT II Hi-Flow reconstitution devices contained within the above-listed batches should be discarded and the replacement devices should be used for the reconstitution of the powder with the provided solvent, as instructed in the Product Information**
- **In case of any delays in receiving replacement devices and if a patient is in possession of an impacted lot, the patient should be advised that they should continue to administer the medicinal products using the devices in their possession.**
- **There is no quality issue with the FEIBA NF drug products or any other components in the pack.**

- **Healthcare professionals should provide the required number of replacement devices with a copy of *Appendix 1, Instructions for patients who self-administer,* included below, to patients who are self-administering medicinal product and are in possession of the impacted lots.**

Background
FEIBA NF may be co-packaged with the BAXJECT II Hi-Flow device that is used for reconstituting the medicinal product prior to administration.

Takeda has decided to voluntarily replace BAXJECT II Hi-Flow reconstitution devices produced by Takeda's contract device manufacturer between October 2021 and January 2022, for use in conjunction with FEIBA NF.

This is a precautionary measure and is due to a potential issue, related to particulate matter that originates in the luer port of the BAXJECT II Hi-Flow reconstitution device co-packaged with the medicinal products mentioned above (See Image in Appendix 1).

It is important to note that there is no quality issue with the FEIBA NF drug product itself. No particulate matter has been identified in the active product or WFI diluent. The safety profiles of all products remain consistent with the product labels. There have been no adverse events identified that were attributable to the presence of particles in the BAXJECT II Hi-Flow devices in our Global Safety databases.

To ensure that patients can continue to receive their needed therapies, **it is important that you carefully read the instructions below and follow them when you are administering these medicinal products.** Additionally, ensure that you communicate these instructions clearly to all patients who self-administer the products or their caregivers, by provision of *Appendix 1: Instructions for patients who self-administer*.

Replacement of Impacted Devices
Takeda will provide replacement BAXJECT II Hi-Flow reconstitution devices to the Healthcare Professionals who have received impacted lots.

Please carefully follow the below instructions to allow patients to continue their treatment using the replacement devices. If awaiting replacement devices and in possession of an impacted lot, patients should be advised that they should continue to administer the medicinal products using the devices in their possession. If you require additional devices, please contact your distributor who provides you with FEIBA NF.

For Healthcare Professionals who administer the impacted batches to patients:

1. You will receive a sufficient quantity of replacement devices to cover the number of units of drug product you have received. Please store the replacement devices alongside the product (in a refrigerator if applicable).
2. Please ensure you carefully follow the instructions for use of the drug product.
3. When prompted in the instructions to open the package of BAXJECT II Hi-Flow device, **discard the device co-packed with the finished product and substitute it with the replacement device you have received.**

4. Follow the remaining instructions for reconstitution and administration of the drug product.

After reconstitution, the solution should be inspected for particulate matter and discoloration prior to administration. Do not use solutions that are cloudy or have deposits.

For Healthcare Professionals who dispense the above-listed batches to patients for self-administration:

5. In case you are dispensing a unit of one the above-listed batches, ensure that, upon dispensing to the patient or caregiver, they are made aware of the situation and provide them with a copy of *Appendix 1: Instructions for Patients who Self-administer.*

6. For patients who have already been dispensed the above-listed lots, contact those patients to establish if they have any unused units remaining. If they do, please arrange provision of the required number of replacement devices, plus a copy of *Appendix 1: Instructions for Patients who Self-administer.*

After reconstitution, the solution should be inspected for particulate matter and discoloration prior to administration. Do not use solutions that are cloudy or have deposits.

Takeda is committed to supply with integrity, and we are working closely with Health Canada to ensure continuity of supply for patients. We understand and sincerely regret the impact this issue has on patients and healthcare professionals.

Call for Reporting
Healthcare professionals and patients are encouraged to report adverse reactions and/or quality problems related to the BAXJECT II Hi-flow reconstitution device, used in combination with FEIBA NF to Takeda Canada.

You can report any adverse events/ side effects associated with the use of health products to Health Canada via the Health Canada's channel https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html or by calling toll-free at 1-866-234-2345.

Company Contact Point
You may also contact our medical information department at 1-800-268-2772 or medinfoCA@takeda.com if you have any questions about the information contained in this letter or the safe and effective use of FEIBA NF.

Sincerely,

Dr. Jefferson Tea
Vice President, Medical & Scientific Affairs
Takeda Canada Inc.

Appendix 1: Patient/Caregiver Instructions on use of the replacement BAXJECT II Hi-Flow reconstitution devices

FEIBA NF:

Strength	DIN	Drug Product Lot #	Labelled BJ II HF Device Lot #'s
2500 IU	02353903	F2W053AE	GR349772
2500 IU	02353903	F2W053AF	GR349772

As a precautionary measure after receiving a small number of complaints, Takeda has decided to voluntarily replace BAXJECT II Hi-Flow reconstitution devices produced by Takeda's contract device manufacturer between October 2021 and January 2022, for use with FEIBA NF.

See image of impacted BAXJECT II Hi-Flow Device below. This device is included inside the medicinal product pack of FEIBA NF.

BAXJECT II Hi-flow Device

The medicinal product itself and diluent is not affected by any quality issues. No particles have been found in the active product or diluent. The safety profiles of all products remain consistent with the product labels.

To ensure that you can continue to use your needed therapies, you will be provided with replacement reconstitution devices by your doctor or pharmacist.

If you were given one of the above-listed batches of FEIBA NF medicinal products, read all the information carefully before you use this medicine because it contains important information for you.

Instructions on how to use the Replacement Baxject II Hi-Flow Reconstitution Device

1. Your doctor or pharmacist will contact you if you have received a product pack containing a BAXJECT II Hi-flow device from the above listed batches.
2. If you still have any unused devices with you, your doctor or pharmacist will give you the required number of replacement BAXJECT II Hi-flow devices
3. If you will receive a product pack from the above-listed batches, your doctor or pharmacist will provide the required number of replacement devices with the drug product.
4. The replacement devices should be stored with the drug product, in the fridge if required. Keep these instructions, you may need to read them again. Please make sure you carefully follow the instructions for use in the package leaflet for the product before you use this medicine.
5. When you reach the step in the instructions that asks you to open the package of Baxject II Hi-Flow device, **discard the device in the box and replace it with the new device given to you by your doctor or pharmacist.**
6. Follow the remaining instructions for reconstitution and administration of the drug product in the package leaflet.

Please contact Canada Medical Information at Takeda at 1-800-268-2772 or medinfoCA@takeda.com if you have any questions.

Takeda is committed to supply with integrity, and we are working to ensure continuity of supply for patients. We understand and sincerely regret the impact this issue has on patients.

Reporting Side Effects
Healthcare providers and patients are encouraged to report side effects and/or quality problems related to the BAXJECT II Hi-flow reconstitution device, used in combination with FEIBA NF to Takeda Canada.

You can report any adverse events/ side effects associated with the use of health products to Health Canada via the Health Canada's channel https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html or by calling toll-free at 1-866-234-2345.

Medical Information
You may also contact our medical information department at 1-800-268-2772 or medinfoCA@takeda.com if you have any questions about the information contained in this letter or the safe and effective use of FEIBA NF.


Takeda