August 28, 2023

Dear Healthcare Provider Letter on Replacement BAXJECT® II Reconstitution Devices Packaged with RECOMBINATE™ [Antihemophilic Factor (Recombinant)] and RIXUBIS® [Coagulation [Factor IX (Recombinant)]

Important Information Requiring Action

Dear Healthcare Provider,

The purpose of this letter is to inform you that Takeda, in agreement with the U.S. Food and Drug Administration (FDA), has decided to voluntarily replace BAXJECT® II reconstitution devices produced by Baxter between October 2021 and January 2022 co-packaged for use in conjunction with RECOMBINATE™ [Antihemophilic Factor (Recombinant)] and RIXUBIS® [Coagulation [Factor IX (Recombinant)].

Takeda has received reports of white particles identified near the luer port of the BAXJECT II (see images below). All reported incidents to date were observed prior to administration, either in the syringe after the drug was reconstituted, or when the luer port cap was removed as part of the preparation process.

It is important to note there is no quality issue with either RECOMBINATE and/or RIXUBIS drug product. No particulate matter has been identified in the active product prior to reconstitution. There were no reported adverse events attributable to the presence of particles in the BAXJECT II device in our Global Safety databases leading to the voluntary replacement of the BAXJECT II reconstitution device. **The safety and efficacy profiles of RECOMBINATE and RIXUBIS remain consistent with the product labels**.

Takeda will provide replacement BAXJECT II reconstitution devices to customers that have received impacted lots for distribution to patients and reconstitution of product per the Instructions for Use.

Replacement of Impacted Devices
The impacted lots of BAXJECT II DEVICES co-packaged with RECOMBINATE and RIXUBIS are listed below.

Product	Lot Number
RECOMBINATE	TRA20812AI
	TRA22803AA
	TRA22804AA
	TRA22806AA
	TRA22806AB
	TRA22807AC
	TRA23803AA

Product	Lot Number
RIXUBIS	TNA21008AL
	TNA21012AE
	TNA21013AJ
	TNA21015AG
	TNA21015AH
	TNA22006AE
	TNA22011AB
	TNA22011AE

- **If you are associated with a dispensing pharmacy**, please evaluate your inventory and shipments to identify any impacted lots.
- Takeda will provide replacement BAXJECT II reconstitution devices to customers that have received impacted lots for distribution to patients.
- If you believe your patient(s) have impacted lots, please notify your patient directly and provide a BAXJECT II replacement and Instructions for Use.
- Upon receipt of the BAXJECT II replacement device, patients should carefully follow the Instructions for Use for preparation and administration of the product.
- In the Instructions for Use, when prompted to open the package of the BAXJECT II device contained within the kit, the patient should discard the original BAXJECT II device and use the new replacement device provided.
- If you are a dispensing pharmacy and need additional BAXJECT II devices or have further questions you can contact Customer Service at 800-423-2090 (9:00 a.m. – 6:00 p.m. EDT) or at customerservice@takeda.com.

We take safety and continuity of supply very seriously and are working urgently to provide replacement BAXJECT II devices to customers.

Reporting Adverse Events
Healthcare providers and patients are encouraged to report adverse reactions and/or quality problems related to the BAXJECT II reconstitution device, RECOMBINATE and/or RIXUBIS to Takeda at 1-877-TAKEDA-7 (1-877-825-3327). You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Medical Information
You may also contact our medical information department at 1-877-TAKEDA-7 (1-877-825-3327) or visit www.recombinate.com or www.rixubis.com if you have any questions about the information contained in this letter or the safe and effective use of RECOMBINATE and/or RIXUBIS.

This letter is not intended as a complete description of the benefits and risks related to the use of RECOMBINATE and/or RIXUBIS. Please refer to the enclosed full Prescribing Information and Medication Guide.

Sincerely,

Tom Koutsavlis
Head, U.S. Medical

Enclosure: RECOMBINATE and RIXUBIS Full Prescribing Information

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Appendix

BAXJECT II Reconstitution Device:

Luer Port on BAXJECT II Reconstitution Device: