



August 28, 2023

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

Dear Valued Patient,

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 device (see images below). All reported incidents to date were observed prior to administration, either when the luer port cap was removed as part of the preparation process or in the syringe after the drug was reconstituted.

It is important to note there is no quality issue with either RECOMBINATE and/or RIXUBIS drug product, and therefore the products are safe for use. No particles have 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 Takeda 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 Prescribing Information.**

Takeda will provide replacement BAXJECT II reconstitution devices to pharmacy providers that have received impacted lots for distribution to patients and reconstitution of product per the Instructions for Use. Please see the following information regarding steps for contacting your pharmacy provider to request replacement BAXJECT II device(s).

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

- Please examine any RECOMBINATE and/or RIXUBIS product in your possession to identify any impacted lots. You can locate the lot number on the outside of the product packaging (see image below).
- **If you have impacted RECOMBINATE and/or RIXUBIS product lots in your possession, please contact your pharmacy provider to request replacement BAXJECT II device(s).** The pharmacy provider will ship the replacement device(s) directly to you.
- Upon receipt of the BAXJECT II replacement device, you should carefully follow the Instructions for Use for preparation and administration of the RECOMBINATE and/or RIXUBIS 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 BAXJECT II device provided.**
- If you have further questions, please contact your pharmacy provider or prescribing healthcare provider directly.

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.

Please know that patient safety and supply continuity are our top priorities, and we are working urgently to provide replacement BAXJECT II devices to customers.

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,

Richard C. Ascroft, RPh, JD
Senior Vice President, Head of Plasma-Derived Therapies BU
and Patient and Market Access



Cheryl Schwartz
Senior Vice President, U.S. Rare Disease Business Unit



Enclosure: RECOMBINATE and RIXUBIS Full Prescribing Information

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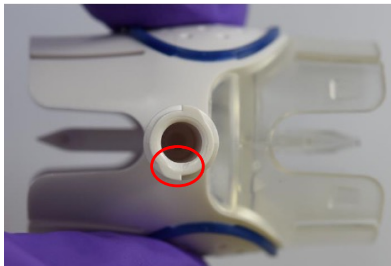


Appendix

BAXJECT II Reconstitution Device:



Luer Port on BAXJECT II Reconstitution Device:



Lot Number on Product Packaging:

