Dear Community Member,

Takeda has brought to our attention an issue with some BAXJECT® II reconstitution devices produced between October 2021 and January 2022 for use in conjunction with RECOMBINATE [Antihemophilic Factor (Recombinant)] and RIXUBIS® [Coagulation Factor IX (Recombinant)] in the U.S. First reported 16 August 2023.

Takeda notified the U.S. Food and Drug Administration (FDA) of reports of plastic particles originating near the luer port of the BAXJECT II device. All reported complaints 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. There have been no reported adverse events attributable to the BAXJECT II device to date. These particles reportedly are too large to transfer from the contaminated medication through the needle, tubing, and to the patient.

BAXJECT II Reconstitution Device

Luer Port on BAXJECT II Reconstitution Device

Takeda reports that ADVATE, ADYNOVATE, and other Takeda products are not affected since the BAXJECT II device is only packaged for use with RIXUBIS and RECOMBINATE in the United States. Takeda is working with the FDA to obtain appropriate guidance for the next steps, and specific lot numbers of affected factor batches are not available currently. In the interim, MASAC recommends patients using RECOMBINATE and RIXUBIS review and visually inspect their medication supply carefully before injection, **both in the bottle and in the syringe**. The reconstituted solution should look colorless to faint yellow, and free from foreign particles. In the event particles are identified in the reconstituted product, please do not administer the product. MASAC advises patients using RECOMBINATE and RIXUBIS® who may have been affected to contact their treatment center if applicable. Alternatively, patients could consider mixing their product using an alternate method, such as using a filter needle attached to the end of the syringe during product mixing. For instructions on how to do this, and how to obtain supplies, contact your treatment center or pharmacy. Patients can also contact their treatment center or pharmacy to re-order new factor product that is not packaged with the BAXJECT II device manufactured in the aforementioned time period. MASAC will continue to work and disseminate additional information as it is available.

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.