

August 20, 2026



PROVIDER ALERT

To: Health Plan of San Joaquin/Mountain Valley Health Plan
("Health Plan") Practitioners, Facilities, and Hospitals
From: Health Plan
Type: Informational/Educational
Subject: **FDA Drug Recall Alert – Tyenne® (tocilizumab-aazg) Injection 400 mg/20 mL Vials**
Business: Medi-Cal Managed Care and Medicare Dual Special Needs Plan (D-SNP)

On August 05, 2026, the Food and Drug Administration (FDA) released a recall announcement on **Tyenne® (tocilizumab-aazg) Injection 400 mg/20 mL Vials**.

This is for informational purposes only. You may or may not have administered the medication. Please disregard if you have not been affected by this recall.

For the complete details regarding this recall announcement, please visit the following web link: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/fresenius-kabi-issues-nationwide-recall-tyenner-tocilizumab-aazg-injection-400-mg20-ml-vials-due?utm_medium=email&utm_source=govdelivery

Fresenius Kabi Issues Nationwide Recall of Tyenne® (tocilizumab-aazg) Injection 400 mg/20 mL Vials Due to Presence of Glass Particles

Company Announcement

August 10, 2026 – LAKE ZURICH, Ill.— Fresenius Kabi, an operating company of the Fresenius Group, is recalling one lot of Tyenne® (tocilizumab-aazg) Injection 400 mg/20 mL (20 mg/mL) 20 mL vials to the user level. An internal investigation at the firm found the product to contain glass particles.

Affected Products

Tyenne® (tocilizumab-aazg) Injection was distributed nationwide in the United States with a first ship date 03/03/2026 and last ship date of 06/09/2026. NDC, lot, and expiration date can be found on the table.

Product Name / Strength	Dosage Form / Package	NDC	Lot Number	Expiration Date
Tyenne® (tocilizumab-aazg) Injection	400 mg/20 mL (20mg/mL) 20 mL vial	65219-0594-20	16UI07	08/2028

What to Do

Fresenius Kabi is notifying its distributors and customers by letter and is arranging for return of the recalled product. If health care facilities have any of the affected lot, they are to immediately discontinue distributing, dispensing, or using the lot and return all units to Fresenius Kabi. Distributors are instructed to immediately notify their customers that has been shipped or may have been shipped, the product involved in this recall.

Consumers with questions regarding this recall can contact Fresenius Kabi USA Quality Assurance at 1-866-716-2459, Monday through Friday, during the hours of 8:00 a.m. to 5:00 p.m. Central Standard Time. Patients should contact their physician or health care provider if they have experienced any problems that may be related to receiving this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to Fresenius Kabi Medical Affairs or Vigilance departments at 1-800-551-7176, Monday through Friday, during the hours of 8:00 a.m. to 5:00 p.m. Central Standard Time or send an e-mail to either productcomplaint.USA@fresenius-kabi.com or adverse.events.USA@fresenius-kabi.com.

Contact Information

Consumers: 1-800-551-7176 productcomplaint.USA@fresenius-kabi.com	Media: Matt Kuhn 1-847-220-3033
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If you have any further questions, please contact your Provider Services Representative, or call our Customer Service Department at 1-888-936-PLAN (7526). You may also visit <https://www.hpsj.com/alerts/> for online access to the documents shared. The most recent information about Health Plan and our services is always available on our website WWW.HPSJ-MVHP.ORG.