COMMUNICATION

COM-2026-030

AUGUST 11, 2026

Recall Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate the latest up-to-date drug recall.

Recall of one Lot of Tyenne® (tocilizumab-aazg) Vial

U.S. Food & Drug Administration Publication Date:

08/11/2026

National Drug Code:

65219-594-20

Product Description:

Tyenne® (tocilizumab-aazg) Injection, 400 mg / 20 mL (20mg/mL) 20 mL vial

Batch (Lot) Number:

16UI07

Expiration Date:

08/2028

Company:

Fresenius Kabi

Questions:

Call Fresenius Kabi USA Quality Assurance at 1-866-716-2459, Monday through Friday (8:00 a.m. to 5:00 p.m. Central Standard Time)

It is for this reason that we are notifying you that on August 11, 2026 the U.S. Food and Drug Administration (FDA) published a drug recall for the following product(s): Tyenne Injection 400 mg/20 mL vial.

Reason for Recall

Fresenius Kabi 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. 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.

The administration of an injectable product containing glass particulates may cause local irritation, pain, or swelling at the infusion site, as well as inflammation of the veins. More seriously, glass particles can cause blockage and clotting in blood vessels, which can cut off blood flow to vital organs, lead to a life-threatening blood clot in the lungs (pulmonary embolism) and cause permanent organ damage or death.

Pharmacy Required Action

Identify if the product is in inventory and immediately stop using and dispensing it. The product should be returned to the place of purchase or as directed in the recall notification.

Advise patients that they should not discontinue using the medication without contacting their healthcare provider. Patients experiencing any problem while taking or using this product must contact their physician.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252-ext.219. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

REFERENCES:

1. U.S. Food and Drug Administration. *Fresenius Kabi Issues Nationwide Recall of Tyenne® (tocilizumab-aazg) Injection 400 mg/20 mL Vials Due to Presence of Glass Particles*. FDA, 11 August 2026. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/fresenius-kabi-issues-nationwide-recall-tyenner-tocilizumab-aazg-injection-400-mg20-ml-vials-due