Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC26-018-CG
August 25, 2026

FDA announced that, 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.

RECOMMENDATIONS

1. 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.

2. Distributors are instructed to immediately notify their customers that have been shipped or may have been shipped, the product involved in this recall.

3. 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.

4. Patients should contact their physician or health care provider if they have experienced any problems that may be related to receiving this drug product.

5. Review your inventory to identify existence of recalled products.

6. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

Cordially,

MC-Rx Pharmacy Services Department

T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507
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Call Box 4908, Caguas, P.R. 00726
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FDA U.S. FOOD & DRUG ADMINISTRATION

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

SUMMARY

Company Announcement Date:	August 10, 2026
FDA Publish Date:	August 11, 2026
Product Type:	Drugs
Reason for Announcement:	Due to Presence of Glass Particles
Company Name:	Fresenius Kabi
Brand Name:	Fresenius Kabi
Product Description:	Tyenne Injection 400 mg/20 mL vial

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.

Risk Statement: 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.

Tyenne® (tocilizumab-aazg) Injection is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs); adult patients with giant cell arteritis; patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis; patients 2 years of age and older with active systemic juvenile idiopathic arthritis; adults and pediatric patients 2 years of age and older with chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome; and certain hospitalized adult patients with COVID-19.

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Recalled product can be identified as follows (with label below):

Product Name/Size	NDC Number	Product Code	Lot Number	Expiration Date	First Ship Date	Last Ship Date
Tyenne® (tocilizumab-aazg) Injection, 400 mg / 20 mL (20mg/mL) 20 mL vial	65219-594-20	590120	16UI07	08/2028	03/03/2026	03/25/2026

Tyenne (tocilizumab-aazg) Injection 400 mg/20 mL (20 mg/mL) 20 mL was distributed nationwide to wholesalers, distributors and direct customers.

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 have 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.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online:** www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm 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.**

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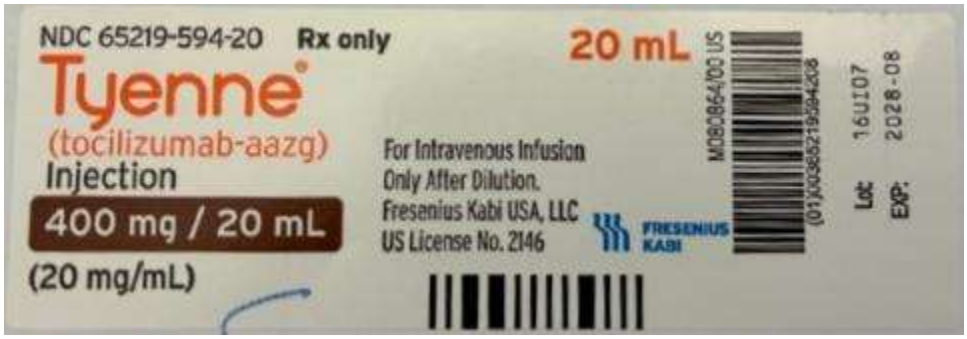
Product Photos



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