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

Date: 08/11/2026

At Prime Therapeutics, we want to help you receive the best possible care. Visit our drug recall site for details: https://www.primetherapeutics.com/drugrecalls.

About this recall:
Fresenius Kabi is recalling one lot of Tyenne (tocilizumab-aazg) Injection 400 mg/20 mL (20 mg/mL) vials (NDC 65219-0594-20) to the user level. An internal investigation found the product contains glass particles. The recalled lot number is 16UI07 with expiration date of 08/31/2028.

Tyenne (tocilizumab-aazg) is indicated for a number of inflammatory conditions, including:

- Certain adult patients with moderately to severely active rheumatoid arthritis
- 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
- Certain hospitalized adult patients with COVID-19

What this means to you:
The administration of an injectable product containing glass particulates may cause local irritation, pain, or swelling at the injection 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.

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 healthcare 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 the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Complete and submit the report Online.
- Regular Mail or Fax: Download form 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.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

For more information regarding this FDA Recall Notification, please refer to the FDA website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/fresenius-kabi-issues-nationwide-recall-tyenner-tocilizumab-aazg-injection-400-mg20-ml-vials-due

FDA contact information for reporting adverse events/quality complaints can be reached online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then selecting prompt #2.