Provider Newsflash
August 2026

FDA Recall – Fresenius Kabi - Tyenne Injection

Purpose of this communication:

We are writing to inform you 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. The affected lot is 16UI07, expiration date 08/2028, NDC 65219-594-20, product code 590120. The impacted product was distributed from March 03, 2026, through March 25, 2026.

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.

What do I need to do?

- Please review the following recall notice: Fresenius Kabi Issues Nationwide Recall of Tyenne® (tocilizumab-aazg) Injection 400 mg/20 mL Vials Due to Presence of Glass Particles | FDA
- Notify impacted patients and facilitate the resolution of the recall, according to the guidelines issued by the manufacturer in the FDA notification.
- Confirm if you have any CareCentrix patients affected by this recall and notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.

Thank you in advance for your cooperation and continued partnership.