FRESENIUS KABI

URGENT DRUG RECALL

August 11, 2026

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

Dear Customer/Healthcare Professional:

This letter is to notify you that Fresenius Kabi USA, LLC ("Fresenius Kabi") is voluntarily recalling the above-mentioned lot of Tyenne® (tocilizumab-aazg) Injection, 400 mg / 20 mL (20 mg / mL) 20 mL vial.

This recall is being performed to the user level. Fresenius Kabi has decided to take this action due to the presence of glass particles. The investigation reveals this issue is limited to this lot. Reference Attachment A for product labeling.

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. No adverse event reports have been received for the above-listed lot to date.

You are required to **DESTROY** all product from the above-mentioned lot number that you have in your possession. To implement this recall, please do the following:

1. Examine your stock **immediately** to determine if you have any product from the affected lot. Quarantine any affected stock. If you are a distributor, immediately notify your customers that have been shipped or may have been shipped this product of this recall and direct them to quarantine and discontinue distributing or dispensing the affected lot. Please have them prepare to **DESTROY** the product. Your notification to your customers may be enhanced by including a copy of this recall notification letter. Your customers may retrieve the recall letter and response form at https://www.fresenius-kabi.com/us/pharmaceutical-product-updates.

2. If you have the affected lot available, **immediately** quarantine and discontinue distributing, dispensing, or using the lot, and **DESTROY** all vials using your current vendor / hauler of non-hazardous regulated medical waste. A credit memo will **NOT** be issued covering the quantity until a letter of destruction is received from you.

3. **PLEASE COMPLETE THE ENCLOSED "URGENT DRUG RECALL RESPONSE FORM" AND SEND IT BACK IMMEDIATELY VIA EMAIL TO FK-NARECALLS@FRESENIUS-KABI.COM OR FAX AT 1-708-649-8630.**

CONTACT NUMBERS: Use the following contact phone numbers. Hours of operation: Monday through Friday 8:00 am to 5:00 pm CST

Number	Department	Reason to Call
(866) 716-2459	Quality Assurance Department	Information on how to return product
(800) 551-7176	Vigilance or Medical Affairs	For clinical/technical information/Adverse Drug Event (ADE) reporting

This recall is being made with the knowledge of the United States Food and Drug Administration (FDA).

We apologize for any inconvenience this voluntary recall may cause you.

Sincerely,

Anthony Giessert, Ph.D.
Senior Vice President, Quality Assurance
Fresenius Kabi USA, LLC

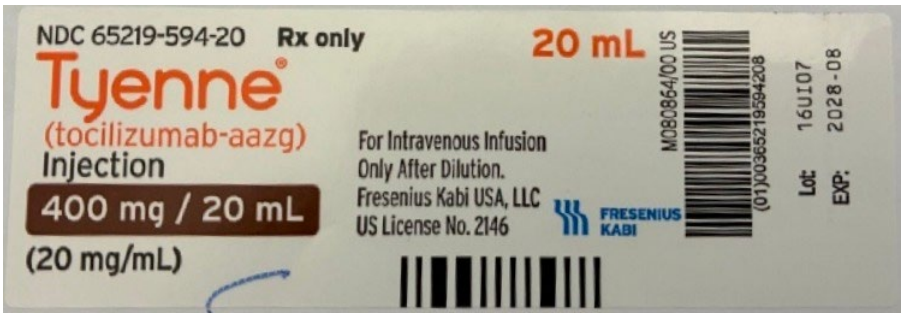
Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047

Main: 847-550-2300
Toll Free: 888-391-6300
www.fresenius-kabi.com/us

FRESENIUS KABI

URGENT DRUG RECALL

Attachment A
Product Labeling



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FRESENIUS KABI

URGENT: DRUG RECALL – Sterile Injectable

URGENT DRUG RECALL RESPONSE FORM

AUGUST 11, 2026

Please complete and fax or email to: 1-708-649-8630 or FK-NARECALLS@FRESENIUS-KABI.COM

To: Fresenius Kabi USA, LLC **Attn:** Quality Assurance Department

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

1. Examine your inventory **immediately** to determine if you have any product from the above-mentioned lot.

2. If so, **immediately** discontinue distribution or dispensing of the affected lot and **DESTROY** all units using your current vendor / hauler of non-hazardous regulated medical waste. A credit memo will NOT be issued covering the quantity until a letter of destruction is received from you.

3. **PLEASE COMPLETE THIS FORM AND SEND IT BACK TO US IMMEDIATELY VIA EMAIL AT FK-NARECALLS@FRESENIUS-KABI.COM OR FAX AT 1-708-649-8630.**

☐ We currently do not have units of the lot number on hand.

☐ We are **DESTROYING** _____ Vials ☐ We are **DESTROYING** _____ Trays/Cartons

4. I have identified and contacted direct account customers that have been shipped or may have been shipped this product. They have prepared to return the product.

YES ☐ I do not have direct account customers ☐

FROM: Hospital (other):_____

Street Address:_____

City, State, Zip code: _____

Phone Number: _____

Email:_____

Signature:_____

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