COMMUNICATION

COM-2024-087

26 DECEMBER 2024

URGENT PLEASE REVIEW

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 information.

U.S. Food & Drug Administration Publication Date:

12/24/2024

Drug Information:

National Drug Code

Prograf® 0.5 mg capsules:

0469-0607-73

Astagraf XL® 0.5 mg capsules:

0469-0647-73

Product Description

Prograf® 0.5 mg capsules: 100 capsules per bottle

Astagraf XL® 0.5 mg capsules: 30 capsules per bottle

Lot Number

Prograf® 0.5 mg capsules: 0E3353D

Astagraf XL® 0.5 mg capsules:

0R3092A

Expiration Date

Prograf® 0.5 mg capsules: 03/2026

Astagraf XL® 0.5 mg capsules:

03/2026

Company:

Astellas Pharma US, Inc

QUESTIONS

Call Astellas Pharma US, Inc at 1-877-575-3437 9 am to 5 pm (EST), Monday through Friday

Prograf® (tacrolimus) 0.5 mg capsules and Astagraf® (tacrolimus extended-release) 0.5 mg capsules

It is for this reason that we are notifying you that on December 24, 2024 the U.S. Food and Drug Administration published a drug recall for the following product(s): Prograf® (tacrolimus) 0.5 mg capsules and Astagraf XL® (tacrolimus extended-release) 0.5 mg capsules.

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.

Reason for Recall:

Astellas Pharma US, Inc. is voluntarily recalling one lot of Prograf® 0.5 mg and one lot of Astagraf XL® 0.5 mg capsules to the consumer level because the bottles of these products may contain empty capsules.

Risk Statement:

Transplant patients who consume empty Prograf® or Astagraf XL® capsules may experience initiation of rejection of the transplanted organ, tissue, or cells, due to underimmunosuppression. In the case of life sustaining organ transplants, such as a heart transplant, if the transplant fails, the consequences of rejection initiated by ingesting empty capsules may be fatal. To date, Astellas has not received any reports of adverse events related to this recall.

PRODUCT DESCRIPTION	NDC	LOT NUMBER	EXP. DATE
Prograf® (tacrolimus) 0.5 mg capsules: 100 capsules per bottle	0469-0607-73	0E3353D	03/2026
Astagraf XL® (tacrolimus extended-release capsules) 0.5 mg capsules: 30 capsules per bottle	0469-0647-73	0R3092A	03/2026

Patients that have an affected lot should contact their physician or healthcare provider. Patients and physicians with questions should contact Astellas Medical Information at 1-800-727-7003 During office hours from 9 am to 5:30 pm EST, Monday through Friday.

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/.

PharmPix Drug Recall Communication Number COM-2024-087 December 2024

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REFERENCES:

1. U.S. Food and Drug Administration. (2024). Astellas Pharma US, Inc. Issues Voluntary Nationwide Recall of One Lot of PROGRAF® 0.5mg (Tacrolimus) and One Lot of ASTAGRAF XL® 0.5mg (Tacrolimus Extended-Release Capsules) Because Bottles Shipped to U.S. May Contain Empty Capsules. Retrieved December 26, 2024, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/astellas-pharma-us-inc-issues-voluntary-nationwide-recall-one-lot-prografr-05mg-tacrolimus-and-one
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program- Available at: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

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