Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC25-001-CG
January 7, 2025

FDA announced that Astellas Pharma US, Inc. (Head of US Commercial: Michael Petroutsas, "Astellas") is voluntarily recalling one lot of PROGRAF® 0.5mg (tacrolimus) and one lot of ASTAGRAF XL® 0.5mg (tacrolimus extended-release) capsules to the consumer level. These products are being recalled because bottles may contain empty capsules

RECOMMENDATIONS

1. Astellas is notifying its customers via a drug recall notification letter and is arranging for the return of impacted product.

2. Wholesalers or pharmacists with questions about the recall process should contact **1-877-575-3437** during office hours 9 am to 5 pm (EST), Monday through Friday.

3. Patients that have an affected lot should contact their physician or healthcare provider.

4. 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.

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.

MC-Rx Pharmacy Services Department

T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507
T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726
MC-Rx.com

FDA U.S. FOOD & DRUG ADMINISTRATION

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

SUMMARY:

Company Announcement Date:	December 23, 2024
FDA Publish Date:	December 24, 2024
Product Type:	Drugs
Reason for Announcement:	Bottles may contain empty capsules.
Company Name:	Astellas Pharma US, Inc.
Brand Name:	Astellas
Product Description:	Tacrolimus and Tacrolimus Extended-Release capsules

COMPANY ANNOUNCEMENT:

FOR IMMEDIATE RELEASE – NORTHBROOK, IL, Dec. 23, 2024 – Astellas Pharma US, Inc. (Head of US Commercial: Michael Petroutsas, "Astellas") is voluntarily recalling one lot of PROGRAF® 0.5mg (tacrolimus) and one lot of ASTAGRAF XL® 0.5mg (tacrolimus extended-release) capsules to the consumer level. These products are being recalled because bottles 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 (for which there is no permanent substitute such as hemodialysis in the case of a failed kidney 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.

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PROGRAF and ASTAGRAF XL are immunosuppressive medicines, used in conjunction with other medicines, to help prevent organ transplant rejection. PROGRAF is used in people who have had kidney, heart, liver, or lung transplants and ASTAGRAF XL is indicated for use in people with kidney transplants.

The affected lot numbers and expiration dates are:

PRODUCT DESCRIPTION	NDC	LOT NO.	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

No other formulations or doses of the product are impacted, and sufficient supply of unaffected stock is available to replace the recalled lots. Product was distributed nationwide to wholesale and retail outlets.

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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.

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**

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