Humana

Pharmacy Solutions®

Drug recall notice for Prograf and Astagraf XL capsules

To assist you in the care of your patients, Humana is alerting you to the recall of one lot of Prograf® (tacrolimus) 0.5 mg and one lot of Astagraf XL® (tacrolimus extended-release) 0.5 mg capsules on Dec. 23, 2024.[1] We recommend you review your medical records and contact all patients for whom you have prescribed this medication to warn them of the recall.

The drug manufacturer, Astellas Pharma US, Inc., is voluntarily recalling these products due to some bottles possibly containing empty capsules.

Prograf and Astagraf XL are immunosuppressive medications that work in combination with other medications for the prevention of organ transplant rejection.

"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," the U.S. Food and Drug Administration said in the drug recall notice, adding that "if the transplant fails, the consequences of rejection initiated by ingesting empty capsules may be fatal."

To date, Astellas Pharma US, Inc. has received no reports of adverse events related to this recall.

Medications included in this recall

Product name	National Drug Code	Lot number	Expiration date
Prograf (tacrolimus) 0.5 mg capsules	0469-0607-73	0E3353D	March 2026
Astagraf XL (tacrolimus extended-release) 0.5 mg capsules	0469-0647-73	0R3092A	March 2026

Information for providers:[1]

- We sent a letter to your Humana-covered patients with a claim for Prograf (tacrolimus) 0.5 mg or Astagraf XL (tacrolimus extended-release) 0.5 mg capsules and asked them to contact their providers if their medication is included in the recall and if they have experienced problems that could be related to using these drug products.
- Providers with questions can contact:
    - Astellas medical information at 800-727-7003, Monday – Friday, 9 a.m. – 5:30 p.m., Eastern time
- Patients can report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting Program online, by phone or by fax.
    - **Online:** Submit the report.
        - Select "Form FDA 3500 - Voluntary Reporting."
    - **Phone or fax:** Download the form.
        - Complete and submit "Form FDA 3500 - Voluntary Reporting" by phone at 800-FDA-1088 (332-1088) or by fax to 800-FDA-0178 (332-0178).

Reference

1. "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," U.S. Food and Drug Administration, last accessed Jan. 8, 2025, 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.