



URGENT: DRUG RECALL

Dear Valued Partner:

This is to inform you of a drug recall at the consumer level.

PRODUCT DESCRIPTION	NDC	UPC CODE	LOT NO.	EXP. DATE
PROGRAF® (tacrolimus) 0.5 mg capsules 100 capsules per bottle	0469-0607-73	3 04690 60773 1	0E3353D	03/2026
ASTAGRAF XL® (tacrolimus extended-release capsules) 0.5 mg capsules 30 capsules per bottle	0469-0647-73	3 04690 64773 7	0R3092A	03/2026

This recall has been initiated due to a product physical issue (empty capsules). 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.

Astellas is directly notifying wholesalers, and pharmacies are being instructed to contact any patients who have received these recalled lots, as well as the prescribing physicians of these patients. At this time, no action is required from you.

No other lots, packages, or formulations are being recalled. Sufficient supply of unaffected stock is available to replace recalled batches.

For medical inquiries, please contact **Astellas Medical Information** at **1-800-727-7003** during office hours from 9 am to 5:30 pm (EST) Monday through Friday.

This recall is being made with the knowledge of the Food and Drug Administration.

Sincerely,


Brian Richardson
Lead – US Contract Management