Astellas – Recall of Astagraf XL® and Prograf® capsules

- On December 24, 2024, Astellas announced a voluntary, consumer level recall of one lot of Astagraf XL (tacrolimus) extended-release capsules and one lot of Prograf (tacrolimus) capsules because some bottles may contain empty capsules.

- Astagraf XL and Prograf were distributed nationwide.

Product Description	NDC#	Lot# (Expiration Date)
Astagraf XL (tacrolimus extended-release capsules) 0.5 mg capsules, 30 count	0469-0647-73	0R3092A (3/2026)
Prograf (tacrolimus) 0.5 mg capsules, 100 count	0469-0607-73	0E3353D (3/2026)

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

- Transplant patients who consume empty Astagraf XL or Prograf 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.

- Anyone with the affected lots on hand should stop distribution and return product.

- Patients that have bottles from the recalled lot of Astagraf XL or Prograf capsules should contact their healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

- Contact Astellas Medical Information by phone at 1-800-727-7003 for questions regarding this recall