

Dec. 24, 2024



Astellas issues voluntary nationwide recall of 1 lot of Prograf 0.5 mg (tacrolimus) and 1 lot of Astagraf XL 0.5 mg (tacrolimus extended-release)

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About this recall:

Astellas is voluntarily recalling one lot of Prograf (tacrolimus) 0.5 mg capsules (NDC 00469-0607-73) and one lot of Astagraf XL (tacrolimus extended-release) 0.5 mg capsules (NDC 00469-0647-73) to the consumer level. These products are being recalled because bottles from the recalled lots may contain empty capsules.

Prograf and Astagraf XL are immunosuppressive medicines, used in combination 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.

What this means to you:

Transplant patients who consume empty Prograf or Astagraf XL capsules may experience initiation of rejection of the transplanted organ, tissue or cells, due to lack of immunosuppression. In the case of life-sustaining organ transplants (such as a heart transplant), if the transplant fails, this may lead to death.

Patients that have a recalled lot should contact their health care provider. Patients and physicians with questions should contact Astellas Medical Information at **800.727.7003**, Monday–Friday, 9 a.m.–5:30 p.m. Eastern Standard Time (EST).