Astellas Issues Voluntary Nationwide Recall of One Lot of Prograf® 0.5 mg (Tacrolimus) and One Lot of Astagraf XL® 0.5 mg (Tacrolimus Extended-Release)

Date: 12/24/2024

At Prime Therapeutics, we want to help you receive the best possible care. Visit our drug recall site for details: https://www.primetherapeutics.com/drugrecalls.

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.

For lot recalls, the lot/batch information and expiration date for the recalled product can be viewed by clicking on the link to the FDA Recall Notification found on the following page.

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 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.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

For more information regarding this FDA Recall Notification, please refer to the FDA website: 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

FDA contact information for reporting adverse events/quality complaints can be reached online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then selecting prompt #2.