Magellan Medicaid Administration

Novartis Issues Voluntary US Nationwide Recall of Two Lots of Sandimmune® Oral Solution (Cyclosporine Oral Solution, USP), 100 mg/mL Due to Crystallization

Date: 11/27/2023

At Magellan Medicaid Administration, we want to help you receive the best possible care. Visit our drug recall site for details: https://www1.magellanrx.com/drug-recalls/.

About this recall:
Novartis is conducting a voluntary nationwide recall at the consumer level of 2 lots of its Sandimmune® Oral Solution (cyclosporine oral solution, USP), 100 mg/mL in the United States (US) due to crystal formation observed in some bottles. Crystallization could potentially result in incorrect dosing. The issue was identified during an investigation of crystallization in a different lot of Sandimmune® Oral Solution (cyclosporine oral solution, USP), 100 mg/mL. No other Sandimmune formulations are impacted.

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 below. **The recalled lots of Sandimmune® Oral Solution has an NDC of 0078-0110-22 and is identified as lot# FX 001500 with an expiration of 9/30/2024 and lot# FC001582 with an expiration date of 9/30/2024.**

Sandimmune® Oral Solution (cyclosporine oral solution, USP), 100 mg/mL, packaged in 50 mL bottles, is indicated for the prophylaxis of organ rejection in kidney, liver, and heart allogeneic transplants. The drug may also be used in the treatment of chronic rejection in patients previously treated with other immunosuppressive agents.

What this means to you:
Crystallization of cyclosporine in Sandimmune Oral Solution is likely to result in non-uniform distribution of the cyclosporine in the product, resulting in under-dosing or over-dosing. There is a reasonable probability that underdosing may result in lower exposures and decrease in efficacy which could ultimately lead to graft rejection and graft loss in transplant patients. Furthermore, over-dosage may manifest itself as cyclosporine toxicity in the long term if over exposure continues.

Novartis is notifying its distributors via a recall notification letter and is arranging for return of the recalled lot from distributors, retailers, and consumers. Additionally, Novartis is notifying health care providers who have prescribed this product to contact their patients. Consumers that have bottles from the recalled lot of Sandimmune Oral Solution (cyclosporine oral solution, USP), 100mg/mL, should contact their health care provider.

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 United States (US) 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/novartis-issues-voluntary-us-nationwide-recall-two-lots-sandimmuner-oral-solution-cyclosporine-oral

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.

