

Novartis issues voluntary US nationwide recall of 2 lots of Sandimmune oral solution (cyclosporine oral solution, USP), 100 mg/mL due to crystallization

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About this recall:

Novartis is conducting a voluntary nationwide recall at the consumer level of two lots of its Sandimmune oral solution (cyclosporine oral solution, USP), 100 mg/mL in the United States 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.

The recalled lots of Sandimmune oral solution has an DNC of 0078-0110-22 and is identified as lot number FX 001500 with an expiration of Sept. 30, 2024, and lot number FC001582 with an expiration date of Sept. 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 nonuniform distribution of the cyclosporine in the product, resulting in underdosing or overdosing. 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, overdosage may manifest itself as cyclosporine toxicity in the long term if overexposure 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), 100 mg/mL, should contact their health care provider.