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Novartis issues voluntary nationwide recall of 1 lot 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 one lot of its Sandimmune oral Solution (cyclosporine oral solution, USP), 100 mg/mL, in the United States due to crystal formation observed in some bottles, which could potentially result in incorrect dosing. No other Sandimmune formulations are impacted.

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.

The affected lot number and expiration date is: FX001691 (expiration date 12/2025). This lot was distributed nationwide to wholesalers across the United States, beginning in April 2023.

What this means to you:

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.

In the event that a patient experiences an adverse reaction or quality problem involving this product, they should immediately contact their health care provider and Novartis to report the event or finding. Patients or health care providers may call the Novartis customer interaction center at **888.NOW.NOVA** (**888.669.6682**), Monday–Friday, 8:30 a.m.–5 p.m. Eastern Time (ET). You can report an adverse event at **Novartis.com/Report** or **USDrugSafety.Operations@Novartis.com**.