Novartis – Recall of Sandimmune® (cyclosporine) oral solution

- On September 11, 2023, Novartis announced a consumer level recall of one lot of Sandimmune (cyclosporine) oral solution because of crystal formation observed in some bottles, which could potentially result in incorrect dosing. No other Sandimmune formulations are impacted.

Product Description	NDC Number	Lot Number (Exp Date)
Sandimmune (cyclosporine) oral solution 100 mg/mL, 50 mL bottle	0078-0110-22	FX001691 (12/2025)

- Sandimmune is indicated for the prophylaxis of organ rejection in kidney, liver, and heart allogeneic transplants.
- 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 under-dosing 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.
- To date, Novartis has not received any reports of adverse events related to this recall.
- Anyone with the affected lot on hand should stop distribution and return product. Patients that have bottles from the recalled lot of Sandimmune oral solution should contact their healthcare provider.
- Contact Novartis at **1-888-669-6682** for questions regarding this recall.