



Recall of Sandimmune[®] (cyclosporine) Oral Solution by Novartis Effective Date: 11/24/2023

On November 24, 2023, Novartis announced a voluntary recall of two lots of Sandimmune oral solution because of crystal formation observed in some bottles, which could potentially result in incorrect dosing. This is an expansion to the recall that was announced September 11, 2023.

Per Novartis, crystallization of cyclosporine is likely to result in non-uniform distribution of cyclosporine in the product, resulting in under-dosing or over-dosing. 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 cause cyclosporine toxicity in the long term if over exposure continues.

You are receiving this notice as our records indicate within the past 60 days you have dispensed the above product to a GA Medicaid FFS member. Please check your inventory to determine if you stock the affected product and notify any affected patients if possible.

You can also contact Novartis at **888-669-6682** (8:30 a.m. – 5:00 p.m. EST, Monday through Friday) for more information.

Sandimmune Recalled by Novartis

Product Description	NDC Number	Lot Number (Exp Date)
Sandimmune (cyclosporine) oral solution 100 mg/mL, 50 mL bottle	0078-0110-22	FX001500 (9/2024); FX001582 (9/2024)

References:

1. FDA Safety Alert. Novartis Issues Voluntary Nationwide Recall of One Lot of Sandimmune[®] Oral Solution (Cyclosporine Oral Solution, USP), 100 mg/mL Due to Crystallization. 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>. Accessed November 27, 2023.
2. FDA Safety Alert. Novartis Issues Voluntary Nationwide Recall of One Lot of Sandimmune[®] Oral Solution (Cyclosporine Oral Solution, USP), 100 mg/mL Due to Crystallization. FDA website. <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/novartis-issues-voluntary-nationwide-recall-one-lot-sandimmuner-oral-solution-cyclosporine-oral>. Accessed November 27, 2023.

Thank you for your continued support.