Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC23-064-CG
November 28, 2023

FDA announced that, 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 US due to crystal formation observed in some bottles, which 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 affected lot numbers and expiration dates are: FX001500 (expiration date 09/2024) and FX001582 (expiration date 09/2024) NDC 0078-0110-22. These lots were only distributed in the US. They were distributed nationwide to wholesalers across the US, beginning in January 2022 and September 2022, respectively.

RECOMMENDATIONS

1. Novartis is notifying its distributors via a recall notification letter and is arranging for return of the recalled lot from distributors, retailers, and consumers.

2. Additionally, Novartis is notifying health care providers who have prescribed this product to contact their patients.

3. Consumers that have bottles from the recalled lot of Sandimmune Oral Solution (cyclosporine oral solution, USP), 100mg/mL, should contact their health care provider.

4. Review your inventory to identify existence of recalled products.

5. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

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

Summary:

Company Announcement Date: **November 24, 2023**
FDA Publish Date: **November 27, 2023**
Product Type: **Drugs**
Reason for Announcement: **Due to crystallization formation**
Company Name: **Novartis Pharmaceuticals Corporation**
Brand Name: **Novartis**
Product Description: **Sandimmune (cyclosporine oral solution, USP) Oral Solution 100 mg/mL**

Company Announcement

FOR IMMEDIATE RELEASE – November 24, 2023 - East Hanover, NJ — 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 US due to crystal formation observed in some bottles, which 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.

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.

Risk Statement: 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. Novartis has not received any reports of adverse events related to this recall, to date.

The affected lot numbers and expiration dates are: FX001500 (expiration date 09/2024) and FX001582 (expiration date 09/2024) NDC 0078-0110-22. These lots were only distributed in the US. They were distributed nationwide to wholesalers across the US, beginning in January 2022 and September 2022, respectively.

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.

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) from 8:30 AM - 5:00 PM ET Monday through Friday**, or may report an adverse event through https://www.novartis.com/report or usdrugsafety.operations@novartis.com.

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:** www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm 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**