COMMUNICATION

COM-2023-072

27
NOVEMBER
2023

URGENT
PLEASE
REVIEW

Recall Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug recall information.

U.S. Food & Drug Administration Publication Date:

11/27/2023

Drug Information:

National Drug Code

00078-0110-22

Product Description

SANDIMMUNE™ (CYCLOSPORINE ORAL SOLUTION, USP) ORAL SOLUTION 100 MG/ML

Lot Number

FX001500, FX001582

Expiration Date

SEPTEMBER 2024

Company:

NOVARTIS PHARMACEUTICALS CORPORATION

QUESTIONS

Call NOVARTIS CUSTOMER INTERACTION CENTER at 888.669.6682, Monday – Friday from 8:30 a.m. to 5:00 p.m. EST.

Sandimmune™ Oral Solution

It is for this reason that we are notifying you that on 11.27.2023 the U.S. Food and Drug Administration published a drug recall for the following product(s): Sandimmune™ Oral Solution (cyclosporine oral solution, USP) 100 mg/mL, packed in 50 mL bottles.

Pharmacy Required Action:

Identify if the product is in inventory and immediately stop using and dispensing it. The product should be returned to the place of purchase or as directed in the recall notification.

Advise patients that they should not discontinue using the medication without contacting their healthcare provider. Patients experiencing any problem while taking or using this product must contact their physician.

Reason for Recall:

Novartis is voluntarily recalling two lots of Sandimmune™ Oral Solution (cyclosporine oral solution, USP), 100 mg/mL in 50mL bottles, to the consumer level, due to crystal formation observed in some bottles, which could possibly lead to incorrect dosing.

They were distributed nationwide to wholesalers across the US, beginning in January 2022 and September 2022, respectively. Sandimmune™ Intravenous Solution 50 mg/mL, Sandimmune™ Oral Capsule 100 mg, and Sandimmune™ Oral Capsule 25 mg have not been affected by this recall.

When crystallization of cyclosporine occurs in Sandimmune™ Oral Solution, it could lead to under-dosing or over-dosing because of the non-uniform distribution of cyclosporine in the product.

To date, Novartis has not received any reports of adverse events related to this recall. Novartis is arranging for return of these recalled lots from distributors, retailers, and consumers. Health care providers that have prescribed this product should contact their patients.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 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.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, ext. 219. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

PharmPix Drug Recall Communication Number COM-2023-072 November 2023

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REFERENCES:

1. U.S. Food and Drug Administration. (2023). Novartis Issues Voluntary US Nationwide Recall of Two Lots of Sandimmune® Oral Solution (Cyclosporine Oral Solution, USP), 100 mg/mL Due to Crystallization. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/novartis-issues-voluntary-us-nationwide-recall-two-lots-sandimmuner-oral-solution-cyclosporine-oral
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program- Available at: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

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