COMMUNICATION

COM-2023-053

13 SEPTEMBER 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:

09.11.2023

Drug Information:

National Drug Code

No NDC reported.

Product Description

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

Lot Number

FX001691

Expiration Date

DECEMBER 2025

Company:

NOVARTIS PHARMACEUTICALS CORP.

QUESTIONS

Call NOVARTIS at 888.669.6682 Monday – Friday from 8:30 a.m. to 5:00 p.m. ET.

Sandimmune™ Oral Solution

It is for this reason that we are notifying you that on 09.11.2023 the US Food and Drug Administration published a drug recall for the following product(s): Sandimmune™ oral solution (cyclosporine oral solution, USP) 100mg/mL.

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 conducting a voluntary nationwide recall at the consumer level of one lot of its Sandimmune™ oral solution in the US due to crystal formation observed in some bottles. Crystallization may result in an uneven distribution of the cyclosporine in the product, resulting in underdosing or overdosing. Underdosing leads to a lower exposure and decrease in efficacy which could ultimately lead to graft rejection and graft loss in transplant patients. Moreover, overdosing could lead to cyclosporine toxicity.

Sandimmune™ oral solution 100mg/mL is packaged in 50mL bottles. No other Sandimmune™ formulations are impacted. Novartis is notifying its distributors via a recall notification letter and is arranging for return of the recalled lot from distributors, retailers, and consumers.

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- Clinical Department. 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-2023-053 September 2023

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REFERENCES:

1. U.S. Food and Drug Administration. (2023). Novartis Issues Voluntary Nationwide Recall of One Lot 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-nationwide-recall-one-lot-sandimmuner-oral-solution-cyclosporine-oral
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

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