COMMUNICATION

COM-2025-032

10 JUNE 2025

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

06/04/2025

Drug Information

National Drug Code

Refer to the table included in the notification

Product Description

Sulfamethoxazole / Trimethoprim Tablets, USP, 400 mg/80 mg

Lot Number

Refer to the table included in the notification

Expiration Date

06/2027

Company

Amneal Pharmaceutical LLC

QUESTIONS

Call Amneal Pharmaceuticals at 833-582-0812 Monday – Friday from 8:00 a.m. to 5:00 p.m. EST.

Sulfamethoxazole / Trimethoprim Tablets

It is for this reason that we are notifying you that on 06.04.2025 the U.S. Food and Drug Administration (FDA) published a drug recall for the following product(s): Sulfamethoxazole / Trimethoprim Tablets, USP, 400 mg/80 mg.

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

Three lots of Sulfamethoxazole/Trimethoprim Tablets, USP, 400 mg/80 mg are being recalled to the consumer level as the tablets may exhibit black spots on the tablet surface due to microbial contamination. The observance of black spots was reported in a product quality complaint.

Risk Statement

Oral products contaminated with Aspergillus may result in serious and life-threatening infections. The use of such products in patients with underlying immunosuppressive conditions increases the concern for serious infections. To date, Amneal Pharmaceuticals has not received reports of adverse events related to this recall. The recalled product was distributed nationwide to wholesalers and distributors between 12/04/2024 to 05/15/2025.

Description of product recalled:

NDC Number	Lot Number	Expiration Date	Distribution Starting Date	Bottle Pack Size
65162-271-10	AM241019	06/2027	12/04/2024	100 count
65162-271-50	AM241019A			500 count
65162-271-10	AM241020			100 count

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 POWERED BY ONEARK

REFERENCES:
1. U.S. Food and Drug Administration. (2025). Amneal Pharmaceutical LLC Issues a Nationwide Recall of Sulfamethoxazole / Trimethoprim Tablets, USP, 400 mg/80 mg Only, Due to Microbial Contamination. Retrieved June 6, 2025, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/amneal-pharmaceutical-llc-issues-nationwide-recall-sulfamethoxazole-trimethoprim-tablets-usp-400
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

urac ACCREDITED Pharmacy Benefit Management

2 Street 1, Suite 500
Guaynabo, PR 00968

Tel. 787.522.5252
Fax 866.912.2830

www.pharmpix.com
FRM-CL-000126-001

CLINICAL PEARLS BY PHARMPIX