Amneal Issues a Nationwide Recall of Sulfamethoxazole/Trimethoprim Tablets, 400 mg/80 mg, Due to Microbial Contamination

Date: 06/02/2025

At Prime Therapeutics, we want to help you receive the best possible care. Visit our drug recall site for details: https://www.primetherapeutics.com/drugrecalls.

About this recall:
Amneal is recalling three lots of Sulfamethoxazole/Trimethoprim Tablets, 400 mg/80 mg (NDCs 65162-0271-10 and 65162-0271-50) to the consumer level as the tablets may exhibit black spots on the surface. The black spots were reported in a product quality complaint and are Aspergillus (a common mold).

For lot recalls, the lot/batch information and expiration date for the recalled product can be viewed by clicking on the link to the FDA Recall Notification found on the following page.

This product is an antibiotic approved for the treatment of urinary tract infections caused by susceptible strains of the following organisms: *Escherichia coli*, *Klebsiella* species, *Enterobacter* species, *Morganella morganii*, *Proteus mirabilis* and *Proteus vulgaris*. It is also indicated for other infections such as ear infections in pediatric patients, acute exacerbations of chronic bronchitis due to susceptible strains of *Streptococcus pneumoniae* in adults, and inflammation of the small intestine (enteritis) caused by susceptible strains of *Shigella* and traveler's diarrhea in adults. This recall pertains only to the 400 mg/80 mg strength and **only to the lots listed at the FDA Recall Notification**. The lot number can be found on the Amneal bottle label or by contacting the pharmacy if you received a pharmacy vial.

What this means to you:
Oral drugs contaminated with Aspergillus may result in serious and life-threatening infections, especially in a patient with a weakened immune system. As of early June, Amneal had not received any reports of adverse events, illnesses or injuries related to this recall.

Amneal is arranging for return of all recalled products. Consumers are instructed to contact Amneal directly for assistance with return of any recalled product and reimbursement information.

Individuals with questions regarding this recall can contact Amneal by:
- Phone: 833-582-0812 Monday to Friday, 8:00 am to 5:00 pm, EST
- Fax: 631-983-2595
- Email to: sulfamethoxazole-trimethoprim-recall@amneal.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.
- Regular Mail or Fax: Download form 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.

This recall is being conducted with the knowledge of the United States (U.S.) Food and Drug Administration.

For more information regarding this FDA Recall Notification, please refer to the FDA website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/amneal-pharmaceutical-llc-issues-nationwide-recall-sulfamethoxazole-trimethoprim-tablets-usp-400

FDA contact information for reporting adverse events/quality complaints can be reached online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then selecting prompt #2.