Humana
Pharmacy Solutions®

Drug recall notice for sulfamethoxazole/trimethoprim tablets

To assist you in the care of your patients, Humana is alerting you to the recall of sulfamethoxazole/trimethoprim 400 mg/80 mg tablets on June 2, 2025.[1] We recommend you review your medical records and contact all patients for whom you have prescribed this medication to warn them of the recall.

The drug manufacturer, Amneal Pharmaceuticals LLC, is recalling these products due to a microbial contamination.

The company said in a U.S. Food and Drug Administration (FDA) drug recall notice that the contaminated products could display black dots on the surface of the tablets.

"Oral products contaminated with Aspergillus may result in serious and life-threatening infections," the FDA drug recall notice stated. "The use of the defective product in patients with underlying immunosuppressive conditions increases the concern for serious infections. To date, Amneal Pharmaceuticals has received no reports of adverse events, illnesses or injuries related to this recall."

The medication is used in the treatment of several conditions, such as "urinary tract infections caused by susceptible strains of the following organisms: Escherichia Coli, Klebsiella species, Enterobacter species, Morganella morganii, Proteus mirabilis and Proteus vulgaris," the FDA notice stated.

Other conditions treated by the medication include acute otitis media in pediatric patients, acute exacerbations of chronic bronchitis caused by susceptible strains of Streptococcus pneumoniae, enteritis caused by susceptible strains of Shigella flexneri and adult traveler's diarrhea.

Medications included in this recall
Visit the FDA website for specific details about the recalled medication.

Product name	National Drug Code	Lot number	Expiration date
sulfamethoxazole/trimethoprim 400 mg/80 mg tablets	65162-271-10	AM241019	June 2027
sulfamethoxazole/trimethoprim 400 mg/80 mg tablets	65162-271-50	AM241019A	June 2027
sulfamethoxazole/trimethoprim 400 mg/80 mg tablets	65162-271-10	AM241020	June 2027

Information for providers:[1]

- We sent a letter to your Humana-covered patients with a claim for sulfamethoxazole/trimethoprim 400 mg/80 mg tablets and asked them to contact their providers if their medication is included in the recall and if they have experienced problems that could be related to using these drug products.
- Providers with questions can contact:
    - Amneal Pharmaceuticals by phone at 833-582-0812, Monday – Friday, 8 a.m. – 5 p.m., Eastern time, or by email at sulfamethoxazole-trimethoprim-recall@amneal.com.
- Patients can report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting Program online, by phone or by fax.

- **Online:** Submit the report.
  - Select “Form FDA 3500 - Voluntary Reporting.”
- **Phone or fax:** Download the form.
  - Complete and submit “Form FDA 3500 - Voluntary Reporting” by phone at 800-FDA-1088 (332-1088) or by fax to 800-FDA-0178 (332-0178).

Reference

1. “Amneal Pharmaceutical LLC Issues a Nationwide Recall of Sulfamethoxazole/Trimethoprim Tablets, USP, 400 mg/80 mg Only, Due to Microbial Contamination,” U.S. Food and Drug Administration, last accessed June 9, 2025, https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/amneal-pharmaceutical-llc-issues-nationwide-recall-sulfamethoxazole-trimethoprim-tablets-usp-400.