

### **Amneal – Recall of sulfamethoxazole/trimethoprim tablets**

- On June 3, 2025, Amneal announced a voluntary, consumer level recall of three lots of sulfamethoxazole/trimethoprim tablets because the tablets may exhibit black spots on the tablet surface due to microbial contamination.
- The products were distributed nationwide between December 4, 2024 and May 15, 2025.

Product Description	NDC#	Lot# (Expiration Date)
Sulfamethoxazole / Trimethoprim Tablets, 400 mg/80 mg, 100 count	65162-271-10	AM241019 (6/2027); AM241020 (6/2027)
Sulfamethoxazole/ Trimethoprim Tablets, 400 mg/80 mg, 500 count	65162-271-50	AM241019A (6/2027)

- Sulfamethoxazole/trimethoprim is 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*
  - Acute otitis media in pediatric patients
  - Acute exacerbations of chronic bronchitis due to susceptible strains of *Streptococcus pneumoniae*
  - Enteritis caused by susceptible strains of *Shigella flexneri*
  - Traveler's diarrhea in adults.
- Oral products contaminated with *Aspergillus* may result in serious and life-threatening infections. The use of the defective product in patients with underlying immunosuppressive conditions increases the concern for serious infections.
- To date, Amneal has received no reports of adverse events, illnesses or injuries related to this recall.
- Anyone with the affected lots on hand should stop distribution and return product.
- Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.