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.
    - Clinical Services identified potentially impacted members and will send notifications to the members and their prescribers.
    - The member letter advises members to contact their prescribers or pharmacy for questions.
- 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.

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- Contact Amneal by phone at **1-833-582-0812** or by email at **sulfamethoxazole-trimethoprim-recall@amneal.com** for questions regarding this recall.