

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

Ascend Laboratories would like to inform you of a product recall involving Cephalexin FOS, 125 mg/5 mL.

An out-of-specification (OOS) result was observed in the related substance test at the sixth month of stability analysis (with conditions set at 25°C± 2°C/60%±5%RH) of Cephalexin for Oral Suspension **USP** 125 mg/5 mL. The individual impurity was identified to be Cephalexin Glucose Adduct. As a precautionary measure, all non-expired batches are being recalled from the market.

Cephalexin is used to treat infections caused by bacteria such as pneumonia and other respiratory infections as well as infections of the bones, skin, ears, genitalia, and urinary tract. Cephalexin is considered a cephalosporin and works by killing infection-inducing bacteria. This medicine is only available by prescription and can only be used to treat patients 15 years of age and older. To date, there have been no adverse events reported by patients who have ingested Cephalexin containing the impurity. Our firm began shipping this product on September 1, 2023.

Product Name	Lot Number	Strength	Expiration Date	Pack Size	NDC	Initial Distribution Date	Quantity Distributed (in bottles)
Cephalexin FOS, 125 mg/5 mL	23141828	125 mg/5mL	May2025	100mL	67877-544-88	September 20,2023	7,008
Cephalexin FOS, 125 mg/5 mL	23141829	125 mg/5mL	May 2025	100 mL	67877-544-88	October 4, 2023	7,008
Cephalexin FOS, 125 mg/5 mL	23142342	125 mg/5mL	June 2025	100mL	67877-544-88	October 16, 2023	6,984
Cephalexin FOS, 125 mg/5 mL	23142343	125 mg/5mL	June 2025	100 mL	67877-544-88	September 1,2023	3,372
Cephalexin FOS, 125 mg/5 mL	23142708	125 mg/5mL	July 2025	100mL	67877-544-88	November 9,2023	7,008

Cephalexin FOS, 125 mg/5 mL	23143526	125 mg/ 5mL	September 2025	200mL	67877- 544-68	December 1,2023	3,360
Cephalexin FOS, 125 mg/5 mL	23144035	125 mg/ 5mL	October 2025	100mL	67877- 544-88	May 1, 2024	7,032
Cephalexin FOS, 125 mg/5 mL	23144036	125 mg/ 5mL	October 2025	200 mL	67877- 544-68	February 2, 2024	3,060
Cephalexin FOS, 125 mg/5 mL	23144269	125 mg/ 5mL	November 2025	200mL	67877 - 544- 68	September 23,2024	564
Cephalexin FOS, 125 mg/5 mL	23144270	125 mg/ 5mL	November 2025	100 mL	67877 - 544- 88	April 25, 2024	7,032
Cephalexin FOS, 125 mg/5 mL	24140026	125 mg/ 5mL	December 2025	100 mL	67877 - 544- 88	June 7, 2024	6,864
Cephalexin FOS, 125 mg/5 mL	24140027	125 mg/ 5mL	December 2025	200mL	67877 - 544- 68	August 28, 2024	252
Cephalexin FOS, 125 mg/5 mL	24144282	125 mg/ 5mL	October 2026	200mL	67877 - 544- 68	March 5, 2025	12