

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.

Zydus Pharmaceuticals (USA) Inc. is extending its previous recall of two lots (M300651 & M300652) of Oxybutynin Chloride Extended-Release Tablets, USP 10 mg from September 21, 2023, to an additional seventeen lots of Oxybutynin Chloride Extended-Release Tablets, USP. The recall is based on an out-of-specification (OOS) result observed during testing of one of the stability samples for lot number M300652 at the six months long term time point. Based on the investigation of this OOS, the identified root cause has an impact on an additional seventeen marketed lots. As such, the seventeen impacted lots of Oxybutynin Chloride Extended-Release Tablets, USP mentioned above are being recalled at the Retail Level.

Product	NDC Number	Lot Number	Expiry Date	Count	Distribution Date	Start Date	Distribution End Date
Oxybutynin Chloride Extended-Release Tablets, USP 5 mg	68382-255-01	M212749	11/2024	100's	05/16/2023		05/31/2023
Oxybutynin Chloride Extended-Release Tablets, USP 5 mg	68382-255-01	M214477	11/2024	100's	05/26/2023		06/14/2023
Oxybutynin Chloride Extended-Release Tablets, USP 5 mg	68382-255-01	M214478	11/2024	100's	04/01/2023		06/27/2023
Oxybutynin Chloride Extended-Release Tablets, USP 5 mg	68382-255-01	M214479	11/2024	100's	06/23/2023		07/05/2023

Tablets, USP 5 mg Oxybutynin Chloride Extended- Release	68382- 255-01	M214480	11/2024	100's	07/03/2023	07/26/2023
Tablets, USP 5 mg Oxybutynin Chloride Extended- Release	68382- 256-01	M213318	11/2024	100's	05/23/2023	06/05/2023
Tablets, USP 10 mg Oxybutynin Chloride Extended- Release	68382- 256-01	M213314	11/2024	100's	05/04/2023	05/19/2023
Tablets, USP 10 mg Oxybutynin Chloride Extended- Release	68382- 256-01	M213315	11/2024	100's	04/01/2023	05/30/2023
Extended- Release Tablets, USP 10 mg Oxybutynin Chloride	68382- 256-01	M214436	11/2024	100's	06/02/2023	06/14/2023
Extended- Release Tablets, USP 10 mg	68382- 256-01	M214437	11/2024	100's	05/25/2023	06/26/2023

Oxybutynin
Chloride

Extended-Release 68382-256-
Tablets, USP 10 mg 01 M214438 11/2024 100's 06/16/2023 06/30/2023

Oxybutynin
Chloride

Extended-Release 68382-256-
Tablets, USP 10 mg 01 M300653 12/2024 100's 06/24/2023 07/12/2023

Oxybutynin
Chloride

Extended-Release 68382-256-
Tablets, USP 10 mg 01 M300654 12/2024 100's 07/03/2023 07/25/2023

Oxybutynin
Chloride

Extended-Release 68382-257-
Tablets, USP 15 mg 01 M211541 10/2024 100's 03/31/2023 04/24/2023

Oxybutynin
Chloride

Extended-Release 68382-257-
Tablets, USP 15 mg 01 M211542 10/2024 100's 04/24/2023 05/22/2023

Oxybutynin
Chloride Extended-

Release Tablets, 68382-257-
USP 15 mg 01 M212746 10/2024 100's 05/19/2023 06/14/2023

Oxybutynin
Chloride Extended-

Release Tablets, 68382-257-
USP 15 mg 01 M300660 12/2024 100's 06/13/2023 07/12/2023