

Product recall: Pfizer - Chantix

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.

Pfizer is expanding the June 9, 2021, recall of the below referenced lots of **Chantix Tablets, 0.5 mg bottles, Chantix Tablets, 1 mg bottles and 0.5/1 mg cartons to the consumer/user level. In addition, four (4) lots have been added to the table below in red.** The recall is due to the presence of N-nitroso-varenicline above the Pfizer established Acceptable Daily Intake (ADI) level.

Product	NDC	Lot Number	Expiration Date	Presentation	Configuration/Count
Chantix (varenicline) Tablets, 0.5 mg	0069- 0468-56	00019213	2022 JAN	Bottles	56 tablets/bottle
Chantix (varenicline) Tablets, 0.5 mg	0069- 0468-56	EC6994	2023 MAY	Bottles	56 tablets/bottle
Chantix (varenicline) Tablets, 1 mg	0069- 0469-56	EA6080	2023 MAR	Bottles	56 tablets/bottle
Chantix (varenicline) Tablets, 1 mg	0069- 0469-56	EC9843	2023 MAR	Bottles	56 tablets/bottle
Chantix (varenicline) Tablets, 0.5/1 mg	0069- 0471-03	00020231	2021 SEP	Cartons containing 2 blister packs	Carton containing one blister pack of 11 0.5 mg tablets and one blister pack containing 42 1 mg tablets
Chantix (varenicline) Tablets, 0.5/1 mg	0069- 0471-03	00020232	2021 NOV	Cartons containing 2 blister packs	Carton containing one blister pack of 11 0.5 mg tablets and one blister pack containing 42 1 mg tablets

Product	NDC	Lot Number	Expiration Date	Presentation	Configuration/Count
Chantix (varenicline) Tablets, 0.5/1 mg	0069- 0471-03	00020357	2021 DEC	Cartons containing 2 blister packs	Carton containing one blister pack of 11 0.5 mg tablets and one blister pack containing 42 1 mg tablets
Chantix (varenicline) Tablets, 0.5/1 mg	0069- 0471-03	00020358	2022 JAN	Cartons containing 2 blister packs	Carton containing one blister pack of 11 0.5 mg tablets and one blister pack containing 42 1 mg tablets
Chantix (varenicline) Tablets, 0.5/1 mg	0069- 0471-03	00020716	2022 JAN	Cartons containing 2 blister packs	Carton containing one blister pack of 11 0.5 mg tablets and one blister pack containing 42 1 mg tablets
Chantix (varenicline) Tablets, 0.5/1 mg	0069- 0471-03	ET1600	01/2023	Cartons containing 2 blister packs	Carton containing one blister pack of 11 0.5 mg tablets and one blister pack containing 42 1 mg tablets
Chantix (varenicline) Tablets, 0.5/1 mg	0069- 0471-03	ET1607	01/2023	Cartons containing 2 blister packs	Carton containing one blister pack of 11 0.5 mg tablets and one blister pack containing 42 1 mg tablets
Chantix (varenicline) Tablets, 0.5/1 mg	0069- 0471-03	ET1609	01/2023	Cartons containing 2 blister packs	Carton containing one blister pack of 11 0.5 mg tablets and one blister pack containing 42 1 mg tablets