Chantix - Pfizer

Pfizer is voluntarily recalling two lots of Chantix 0.5mg Tablets, two lots of Chantix 1 mg Tablets, and eight lots of a Chantix kit of 0.5mg/1 mg Tablets to the patient (consumer/user) level due to the presence of a nitrosamine, N-nitroso-varenicline, above the Pfizer established Acceptable Daily Intake (ADI) level.

Long-term ingestion of N-nitroso-varenicline may be associated with a theoretical potential increased cancer risk in humans, but there is no immediate risk to patients taking this medication. The health benefits of stopping smoking outweigh the theoretical potential cancer risk from the nitrosamine impurity in varenicline.

Chantix is a treatment to help patients quit smoking and is intended for short-term use. Patients currently taking Chantix should consult with their doctor or pharmacy to confirm if they received an affected lot, and if appropriate, about alternative treatment options. To date, Pfizer has not received any reports of adverse events that have been related to this recall.

The NDC, Lot Number, Expiration Date, and Configuration details for Chantix Tablets is indicated in the table below. The product lots were distributed nationwide to wholesalers and Distributors in the United States and Puerto Rico from June 2019 to June 2021.

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

As communicated by FDA, there is no immediate risk to patients taking Chantix.[iv] Patients who are taking this product should consult with their health care provider or pharmacy to determine if they have the affected product lots. Patients with the affected lots should contact Stericycle Inc. at 888-276-6166 (Mon.-Fri. 8:00 am - 5:00 pm ET) for instructions on how to return their product and obtain reimbursement for their cost.

Healthcare Professionals with questions regarding this recall can contact Pfizer using the below information.

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Pfizer Medical Information	800-438-1985, option 3 (Mon.-Fri. 9 am-5 pm ET) www.pfizermedinfo.comExternal Link Disclaimer	For medical questions regarding the product
Pfizer Drug Safety	800-438-1985, option 1 (24 hours a day; 7 days a week)	To report adverse events and product complaints