Clifton Health Department
Food Recall Notification

Food/Drug/Pet Recall: Chantix

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.

Nitrosamines are common in water and foods, including cured and grilled meats, dairy products and vegetables. Everyone is exposed to some level of nitrosamines. These impurities may increase the risk of cancer if people are exposed to them above acceptable levels over long periods of time.

Chantix is a treatment to help patients quit smoking and is intended for short term use. People who smoke cigarettes are 15 to 30 times more likely to get lung cancer than people who do not smoke.ii Smoking is also associated with many other cancers.iii CHANTIX has a safety profile that has been established over 15 years of marketing authorization and through a robust clinical program. Pfizer believes the benefit/risk profile of CHANTIX remains positive. Patients currently taking Chantix should consult with their doctor 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 and photos of the products can be found at the end of this press release. 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
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

Pfizer has notified their direct consignees by letter to arrange for return of any recalled product.

Wholesalers and distributors with an existing inventory of the lots, listed in the table above, should stop use and distribution and quarantine the product immediately.

If you have further distributed the recalled product, please notify any accounts or additional locations which may have received the recalled product from you. Please conduct a sub-recall to those accounts and communicate this recall information immediately. Please request they

immediately cease distribution of the affected product and promptly contact Stericycle at 888-276-6166 (Mon.-Fri. 8:00 am - 5:00 pm ET) to obtain a Business Reply Card (BRC) to initiate the return process.

If you received free product through the Pfizer Patient Assistance Program (PAP) or the Pfizer Institutional Patient Assistance Program (IPAP), please check your stock immediately against the table above. If you have any of the affected product lots in your inventory, please follow the instructions above for returning the product to Stericycle Inc. Additionally, if you are aware of any patients to whom you dispensed the affected lots who still may have the product in their possession, please ask them to return the product to you and then follow the instructions above for returning the product to Stericycle Inc. To request replacement product for any Pfizer PAP or Pfizer IPAP product you return, please contact 833-203-2776 (Mon.-Fri. 8:00 am - 6:00 pm ET).

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.
* * *
Pfizer Medical Information 800-438-1985, option 3 (Mon.-Fri. 9 am-5 pm ET)
www.pfizermedinfo.com
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
Contact Center Contact Information Area of Support
Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.
. Complete and submit the report Online
. Regular Mail or Fax: Download form or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.