Pfizer Expands Voluntary Nationwide Recall to include All Lots of CHANTIX® (varenicline) Tablets Due to N-Nitroso Varenicline Content

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FOR IMMEDIATE RELEASE - NEW YORK, NY., September 16, 2021 - Pfizer is voluntarily recalling all lots of Chantix 0.5 mg and 1 mg Tablets to the patient (consumer/user) level due to the presence of a nitrosamine, N-nitroso-varenicline, at or above the FDA interim acceptable intake limit. As alternative suppliers have been approved in the United States, Pfizer is undertaking this precautionary measure.

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.[i]

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, as well as with cardiovascular disease and lung disease.[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 healthcare provider about alternative treatment options. To date, Pfizer has not received reports of adverse events assessed to be related to this recall.

The NDC, Lot Number, Expiration Date, and Configuration details for Chantix Tablets are indicated in Appendix A. Photos of the products can be found in Appendix B. The products were distributed nationwide to Wholesalers and Distributors in the United States, US Virgin Islands and Puerto Rico from May 2019 to September 2021.

Pfizer places the utmost emphasis on patient safety and product quality at every step in the manufacturing and supply chain process. Pfizer has notified their direct consignees by letter to arrange for return of any recalled product.

Wholesalers and Distributors with an existing inventory of Chantix tablets, 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 product and promptly contact Stericycle at 888-276-6166 (Mon.-Fri. 8:00 am - 5:00 pm ET) to obtain a Business Reply Form (BRF) 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. If you have any of the product in 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 products and 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. For any questions related to Pfizer PAP or Pfizer IPAP product, 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 to determine if alternate treatments are available. Patients with Chantix Tablets 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.

Contact Center	Contact Information	Area of Support
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

Adverse events or product complaints experienced with the use of this product may also 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**:
- **www.fda.gov/medwatch/report.htm**

- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm 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 executed with the knowledge of the U.S. Food and Drug Administration.

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Appendix A: Recalled Product Details

PRODUCT: Chantix Tablets, 0.5 mg
NDC: 0069-0468-56
SIZE: Bottle of 56 Tablets
EXPIRATION DATE: January 2022 - May 2023
LOT NUMERS:

00019213	DM9007	EC6994	EN8362
CY6861	DM9008	EN5725	EN8467

PRODUCT: Chantix Tablets, 1 mg
NDC: 0069-0469-56
SIZE: Bottle of 56 Tablets
EXPIRATION DATE: September 2021 – December 2023
LOT NUMBERS:

00018777	00021024	CW1572	DF5280	DY7987	EN5694
00019289	00021073	CW1573	DF5281	EA6080	EN5695
00019593	00021074	CW1574	DF5282	EC9841	EP1717
00019682	CW1565	CW1575	DR5086	EC9842	EP1718
00019846	CW1566	CW1578	DR5092	EC9843	EP1719
00019977	CW1567	CW1579	DR5093	EC9847	EW2012
00020295	CW1568	CW1581	DR5094	EC9848	EW3854
00020448	CW1569	DF5277	DT3885	EE1011	EW3865
00020458	CW1570	DF5278	DW4148	EM1069	EX2102
00020480	CW1571	DF5279	DW4152	EM1070	EX2103

PRODUCT: Chantix Tablets, 1 mg
NDC: 0069-0469-03
SIZE: Carton containing 4 blister packs of 14 tablets each
EXPIRATION DATE: September 2021 – June 2023
LOT NUMBERS:

00019431	00021421	00022765	DR2614	DY7060	EE9391
00019542	00021422	00022766	DX4576	DY9367	EF2346
00019543	00021423	00023134	DX5870	DY9473	EM4805
00019544	00022136	00023135	DX5871	DY9475	EM4807
00020814	00022174	00023747	DX5872	DY9476	EN2005
00020815	00022175	00023748	DX5873	DY9505	ET1601
00020907	00022176	DL3896	DX7805	EC5910	ET1605
00020965	00022177	DL7779	DY6078	EC5913	ET1606

PRODUCT: Chantix Tablets, 0.5/1 mg
NDC: 0069-0471-03
SIZE: Carton containing one blister pack of 11 0.5 mg tablets and one blister pack containing 42 1 mg tablets
EXPIRATION DATE: August 2021 – January 2023
LOT NUMBERS:

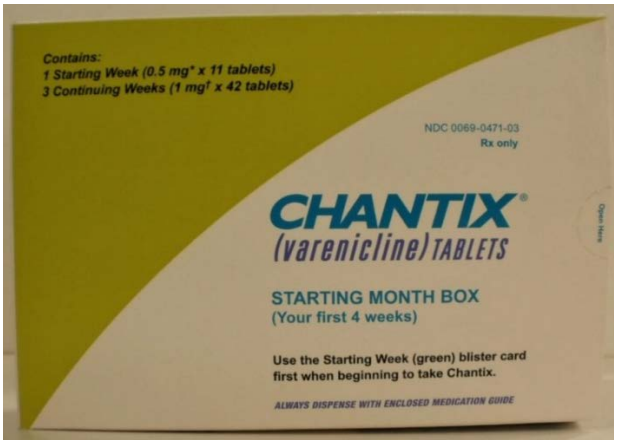
00018522	00020358	00021688	00022851	DM0277	ET1607
00018523	00020716	00021788	00023136	DY4470	ET1609
00018739	00020813	00021789	00023137	EC5911	ET1611
00018740	00021288	00021790	00023190	EC5912	
00020231	00021289	00021791	00023448	ED6814	
00020232	00021420	00021792	DM0275	ET1600	
00020357	00021687	00022819	DM0276	ET1603	

Appendix B: Product Photos

Chantix (varenicline) Tablets 0.5 mg Tablets

Chantix (varenicline) Tablets 1 mg Tablets

Chantix (varenicline) Tablets, 0.5/1 mg Tablets



Chantix (varenicline) Tablets, (1 mg x 56 tablets)

References:

[i] https://www.fda.gov/drugs/drug-safety-and-availability/information-about-nitrosamine-impurities-medications

[ii] U.S. Centers for Disease Control and Prevention. What Are the Risk Factors for Lung Cancer? https://www.cdc.gov/cancer/lung/basic_info/risk_factors.htm Updated September 2020. Accessed June 2021.

[iii] U.S. Department of Health and Human Services. Smoking Cessation. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2020.

[iv] https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerts-health-care-professionals-and-patients-voluntary-recall-varenicline-chantix-warehouse