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

Friday, September 17, 2021 - 03:44pm

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 NUMBERS:

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-andavailability/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/fdaalerts-health-care-professionals-and-patients-voluntary-recallvarenicline-chantix-warehouse

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