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

Media Contact:
Eamonn Nolan
212-733-4626
Eamonn.Nolan@pfizer.com

FOR IMMEDIATE RELEASE - NEW YORK, NY., August 13, 2021.

Pfizer is voluntarily recalling an additional four lots of Chantix 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.[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.[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 with the four additional lots. 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	00018522	2021 AUG	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	00018523	2021 AUG	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	00018739	2021 AUG	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	00018740	2021 AUG	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	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

Product	NDC	Lot Number	Expiration Date	Presentation	Configuration/Count
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 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 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.

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.

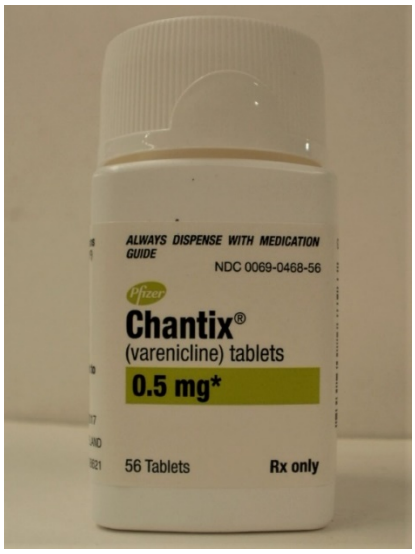
- Complete and submit the report **Online**:
- **www.fda.gov/medwatch/report.htm**
- **Regular Mail or Fax**: Download form **www.fda.gov/MedWatch/getforms.htm** or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

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

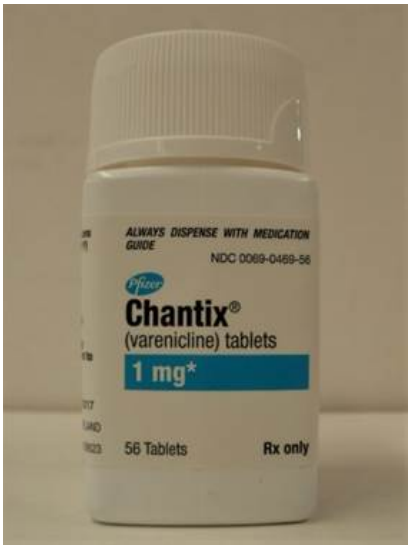
# # # # #

Product Photos

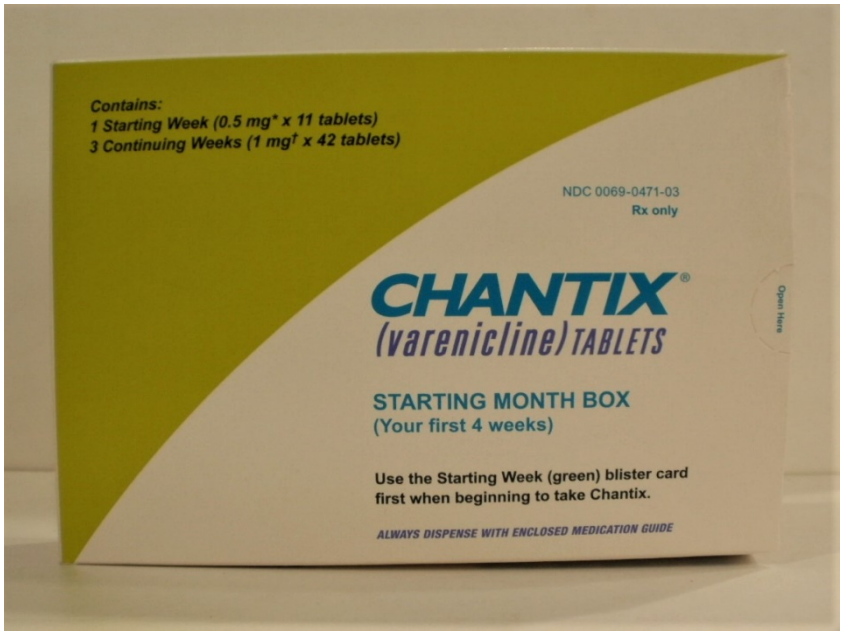
Chantix (varenicline) Tablets
0.5 mg Tablets



Chantix (varenicline) Tablets
1 mg Tablets



Chantix (varenicline) Tablets, 0.5/1 mg 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 and Cancer (Fact Sheet). Atlanta, GA: US Dept 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; 2014.

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