# URGENT: DRUG RECALL EXPANSION

July 19, 2021

## UPDATE TO NOTIFICATION DATED JUNE 9, 2021

**Chantix® (varenicline) Tablets,** 0.5 mg Tablets
**Chantix® (varenicline) Tablets,** 1 mg Tablets
**Chantix® (varenicline) Tablets,** 0.5/1 mg Tablets

| **Multiple NDCs and Lots Affected** |
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| Please refer to the tables on page 4 for a complete listing of the affected product lot numbers. |

Dear Customer;

Pfizer is voluntarily expanding the June 9, 2021 recall of the below referenced lots of **Chantix Tablets, 0.5 mg bottles, Chantix Tablets, 1 mg bottles and 0.5/1 mg cartons to the consumer/user level. In addition, four (4) lots have been added to the table below in red.** The recall is due to the presence of 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. Based on the safety assessment conducted, including an evaluation of safety surveillance data and a toxicological evaluation to establish an Acceptable Daily Intake (ADI), which incorporated numerous conservative assumptions, Pfizer believes that the benefit/risk profile of Chantix remains positive. Although a theoretical excess lifetime cancer risk from N-nitroso-varenicline may exist, it is considered to be low based on currently available data. Nitrosamines are common in water and foods, including cured and grilled meats, dairy products and vegetables. Everyone is exposed to some level of nitrosamines.

To date, Pfizer has not received reports of any adverse events associated with this issue.

***FEDERAL REGULATION 21 CFR 7.49 (d) RESPONSIBILITY OF RECIPIENT STATES: "CONSIGNEES THAT RECEIVE A RECALL COMMUNICATION SHOULD IMMEDIATELY CARRY OUT THE INSTRUCTIONS SET FORTH BY THE RECALLING FIRM …" PFIZER RECOMMENDS THAT YOU RESPOND TO THIS RECALL EVEN IF YOU DO NOT HAVE THE RECALLED PRODUCT. TO RESPOND, COMPLETE THE REQUESTED INFORMATION ON THE ENCLOSED POSTAGE-PAID BUSINESS REPLY CARD (BRC) AND RETURN IT, AS***

***DIRECTED, WITHIN FIVE (5) BUSINESS DAYS.*** If you have any questions about responding to this letter, please contact Stericycle Inc. at 888-276-6166 (Mon.-Fri. 8:00 am – 5:00 pm ET).

The recall of the below referenced lots of Chantix (varenicline) tablets is being conducted to the **Consumer/User Level**.

**Instructions for Wholesalers, Retailers, Hospitals and Health Care Providers:**
Our records indicate that you may have received shipment of the affected lots, which were distributed between June 30, 2019 to June 1, 2021. Please check your stock immediately to identify whether you have bottles/cartons from any of the recalled lots. If you have any of the affected product in your inventory, please stop distribution and quarantine the product immediately. Promptly return it to Stericycle Inc.; 2670 Executive Drive, Suite A; Indianapolis, IN 46241; Attn: Event 6503 using the enclosed pre-paid UPS label. All returns are requested to be completed within six months of this notice date. If you received this notification without the prepaid UPS label and Business Reply Card (BRC), require additional shipping labels, or have questions regarding the return procedure, please contact Stericycle Inc. at 888-276-6166 (Mon.-Fri. 8:00 am – 5:00 pm ET).

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 and quarantine the affected product. Promptly contact Stericycle at 888-276-6166 (Mon.-Fri. 8:00 am – 5:00 pm ET) to obtain a BRC to initiate the return process.

If the affected product lots have been dispensed to patients, please notify these customers regarding this recall.

Reimbursement for the returned product will be made by credit memorandum. If you have any questions regarding the reimbursement, please contact your Pfizer Customer Service Representative at 800-533-4535 (Mon.-Fri. 8:00 am - 5:30 pm ET).

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 below. 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 am-6 pm ET).

**Instructions for Patients:**
Patients who are taking this product should consult with their health care provider or pharmacy to determine if they have the affected product lots, and if appropriate, about alternative treatment options. 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.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration. We appreciate your immediate attention and cooperation, and sincerely regret any inconvenience this action may cause you. If you have any questions regarding this recall, please call the appropriate contact center below.

| 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 | To report adverse events and product complaints |
| Stericycle, Inc. | 888-276-6166 (Mon.-Fri. 8 am-5 pm ET) | For product returns and reimbursement questions |

Adverse events or quality 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.

Sincerely,

Lou Dallago
Vice President
US Trade Group

**Chantix® (varenicline) Tablets,** 0.5 mg Tablets
**Chantix® (varenicline) Tablets,** 1 mg Tablets
**Chantix® (varenicline) Tablets,** 0.5/1 mg Tablets

| 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 |

**Chantix (varenicline) Tablets,** 0.5 mg Tablets


**Chantix (varenicline) Tablets,** 1 mg Tablets


**Chantix (varenicline) Tablets,** 0.5/1 mg Tablets