**July 20th, 2021** **COM-2021-036**

# RECALL NOTIFICATION

**FDA PUBLICATION DATE: July 19, 2021**

**DRUG NAME: CHANTIX**

**COMPANY: Pfizer**

**REASON: Contains N-Nitroso Varenicline content above ADI level**

**Dear provider of pharmaceutical services,**

PharmPix is committed to the health and wellness of our members. Therefore, the clinical team wants to communicate the latest up-to-date information on drug recalls. For this reason, we are notifying that on July 19th, 2021, the U.S. Food and Drug Administration (FDA) published a voluntary drug recall for various lots of Chantix™ manufactured by Pfizer.

The voluntary recall is due to the presence of a nitrosamine, N-nitroso-varenicline. The ingredient levels were above the Pfizer Acceptable Daily Intake (ADI). This impurity may increase cancer risk in humans with long-term use. The company communication states that there is no immediate risk to patients taking this medication. No adverse events have been reported related to the recalled drug.

**Affected product:**

| NDC | Product description | Lot # | Expiration Date |
|---|---|---|---|
| 00069-0468-56 | Chantix™ (varenicline) Tablets, 0.5 mg – Bottle of 56 tabs | 00019213<br>EC6994 | 2020 JAN 2023 MAY |
| 00069-0469-56 | Chantix™ (varenicline) Tablets, 1 mg - Bottle of 56 tabs | EA6080<br>EC9843 | 2023 MAR<br>2023 MAR |
| 00069-0471-03 | Chantix (varenicline) Tablets, 0.5/1 mg -Blister Packs | 00020231<br>00020232<br>00020357<br>00020358<br>00020716<br>ET1600<br>ET1607<br>ET1609 | 2021 SEP<br>2021 NOV<br>2021 DEC<br>2022 JAN<br>2022 JAN<br>2023 JAN<br>2023 JAN<br>2023 JAN |



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**Pharmacy required action(s):**

- Identify if the product is in inventory and immediately stop using and dispensing it. The product should be returned to the place of purchase or as directed in the recall notification.
- Advise patients that they should not discontinue using the medication without contacting their healthcare provider.
- Patients experiencing any problem while taking or using this product must contact their physician.

**Contact information:**

Patients:

- Should contact Stericycle Inc. at 888-276-6166 (Mon.-Fri. 8:00 am - 5:00 pm ET) for instructions on returning their product and obtaining reimbursement for their cost.
- For those patients who received the free product through the Pfizer Patient Assistance Program (PAP) or the Pfizer Institutional Patient Assistance Program (IPAP), return the recalled product using the information above. For the product, replacement contact Stericycle Inc. 833-203-2776 (Mon.-Fri. 8:00 am – 6:00 pm ET)

Healthcare Professionals:

- Please, contact:
  - 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

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program in any of the following ways:

- Complete and submit the MedWatch Online Voluntary Reporting Form online.
- Download FDA Form 3500 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.

Additional information can be found at MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, please call us at 787-522-5252, Clinical Department. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

PharmPix Clinical Department

**Reference(s):**


- U.S. Food and Drug Administration. (2021). Pfizer Issues a Voluntary Nationwide Recall for Twelve Lots of CHANTIX® (Varenicline) Tablets Due to N-Nitroso Varenicline Content. Retrieved from: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pfizer-issues-voluntary-nationwide-recall-twelve-lots-chantixr-varenicline-tablets-due-n-nitroso
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program- Available at: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda




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