DOCTORS HEALTHCARE PLANS, INC.

FDA Drug Recall

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

09/16/2021

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's interim acceptable intake limit. As alternative suppliers have been approved in the United States (US), Pfizer is undertaking this precautionary measure. This is an expansion of previously announced recalls.

Long-term ingestion of N-nitroso-varenicline may be associated with a theoretical increased cancer risk in humans, but there is no immediate risk to patients taking this medication. The health benefits from stopping smoking outweigh the 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.

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. 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 professional (HCP) about alternative treatment options. To date, Pfizer has not received reports of adverse events assessed to be related to this recall.

Recalled product details are found in Appendix A on the following page. The lot numbers and photos for recalled products are provided at the link on the following page. The products were distributed nationwide to wholesalers and distributors in the US, US Virgin Islands, and Puerto Rico from May 2019 to September 2021. 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 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. 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. For any questions related to Pfizer PAP or Pfizer IPAP product, please contact 833-203-2776 (Monday through Friday, 8 am to 6 pm ET).

As communicated by the FDA, there is no immediate risk to patients taking Chantix. Patients who are taking this product should consult with their HCP to determine if alternative treatments are available. Patients with Chantix tablets should contact Stericycle at 888-276-6166 (Monday through Friday, 8:00 am to 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.

Pfizer Medical Information	800-438-1985, option 3 (Monday to Friday, 9 am to 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 reactions or quality problems experienced with the use of this product may 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/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda
- Regular Mail or Fax: Download form: www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting 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 conducted with the knowledge of the U.S. Food and Drug Administration.

Source: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/pfizer-expands-voluntary-nationwide-recall-include-all-lots-chantixr-varenicline-tablets-due-n