RXADVANCE
136 Turnpike Road
Southborough, MA 01772

Varenicline (Chantix) Recall Alert

Date of Notice: 7/20/2021

Brief Description of Recall Alert

Pfizer is voluntarily recalling two lots of Chantix 0.5mg Tablets, two lots of Chantix 1 mg Tablets, and eight lots of a Chantix kit of 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.

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[i] Smoking is also associated with many other cancers. 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.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
Chantix (varenicline) Tablets, 0.5 mg	0069-0468-56	0019213 EC6994	1/2022 05/2023
Chantix (varenicline) Tablets, 1 mg	0069-0469-56	EA6080 EA9843	03/2023 03/2023
Chantix (varenicline) Tablets, 0.5/1 mg	0069-0471-03	00020231 00020232 00020357 00020358 00020716 ET1600 ET1607 ET1609	09/2021 11/2021 12/2021 01/2022 01/2022 01/2023 01/2023 01/2023

Prescriber Information

Healthcare Professionals with questions regarding this recall can contact Pfizer using the below information.

Pfizer Medical Information	800-438-1985, option 3 (Mon.-Fri. 9 am-5 pm ET) www.pfizermedinfo.comExternal Link Disclaimer	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

Patients and health care professionals should report any adverse reactions with varenicline to FDA's MedWatch program to help the agency better understand the scope of the problem:

- Complete and submit the report online at www.fda.gov/medwatch/report.htm
- Download and complete the appropriate form, then submit it via fax at 1-800-FDA-0178

Member Information

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.

RxAdvance Response

Members should continue taking Chantix until a doctor or pharmacist provides replacement drug (if needed) or a different treatment option.