RXADVANCE
136 Turnpike Road
Southborough, MA 01772

Varenicline (Chantix) Recall Alert

Date of Notice: 9/16/2021

Brief Description of Recall Alert

Pfizer is voluntarily recalling all lots of Chantix 0.5 mg and 1 mg tablets due to the presence of N-nitroso-varenicline at or above the Food and Drug Administration (FDA) acceptable intake limits.

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. Smoking is also associated with many other cancers, as well as with cardiovascular disease and lung disease.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
Chantix (varenicline) tablets, 0.5 mg	0069-0468-56	All lots	All dates
Chantix (varenicline) tablets, 1 mg	0069-0469-56	All lots	All dates
Chantix (varenicline) tablets, 1 mg	0069-0469-03	All lots	All dates
Chantix (varenicline) tablets, Starting Month Pak, 0.5 & 1 mg	0069-0471-03	All lots	All dates

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

To date, Pfizer has not received reports of adverse events assessed to be related to this recall. 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. Patients who are taking this product should consult with their health care provider or pharmacy to determine if they have one of the affected lots. Patients with the affected lots should contact Stericycle Inc. at 888-276-6166 (Monday through Friday, 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.