RXADVANCE
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Varenicline (Chantix) Recall Alert

Date of Notice: 7/2/2021

Brief Description of Recall Alert

FDA is alerting patients and health care professionals to Pfizer's voluntary recall of nine lots of the smoking cessation drug, varenicline (brand name Chantix), to the warehouse level. The company is recalling varenicline because it may contain levels of a nitrosamine impurity, called N-nitroso-varenicline, above FDA's acceptable intake limit. N-nitroso-varenicline may be associated with a potential increased cancer risk in humans, but there is no immediate risk to patients taking this medication. An increased cancer risk would be associated with long-term use, and the health benefits of stopping smoking outweigh the cancer risk from the nitrosamine impurity in varenicline.

N-Nitroso-varenicline belongs to the nitrosamine class of compounds, some of which are classified as probable or possible human carcinogens (substances that could cause cancer), based on laboratory tests such as rodent carcinogenicity studies. Although there are no data available to directly evaluate the carcinogenic potential of N-nitroso-varenicline, information available on closely related nitrosamine compounds was used to calculate lifetime exposure limits for N-nitroso-varenicline.

Pfizer is recalling the varenicline lots currently stored in warehouses. FDA recommended Pfizer revise its recall to the consumer level in order to take into account the product currently on the market, but the company has not yet done so.

In addition to the voluntary recall, Pfizer is holding release of varenicline to the U.S. market until it can confirm N-nitroso-varenicline levels below what the company considers to be acceptable.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
Varenicline (Chantix)	0069-0471-03	00020231 00020232 00020357 00020358 00020716 ET1607 ET1609	9/30/2021 11/30/2021 12/31/2021 1/31/2022 1/31/2022 1/31/2023 1/31/2023
Varenicline (Chantix)	0069-0468-56	00019213 EC6994	1/31/2022 5/31/2023

Prescriber Information

FDA has determined the recalled varenicline poses an unnecessary risk to patients. Therefore, FDA recommends health care professionals consider other available treatment options for the patient's medical condition. If you have varenicline samples from this company, quarantine them, and do not provide them to patients. Contact Pfizer directly if you have questions regarding product return or disposal.

FDA is actively considering options to help mitigate a shortage of varenicline in the U.S. including working to identify an alternate supplier. The agency is continuing to investigate the presence of N-nitroso-varenicline in varenicline products and will provide more information as it becomes available.

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

Continue taking your current medicine until your doctor or pharmacist gives you a replacement or a different treatment option. Contact your health care professional if you are taking this medication and have questions about your health.

RxAdvance Response

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