

Pfizer – Recall of Chantix® (varenicline) to warehouse level

- On July 2, 2021, the [FDA announced](#) a voluntary, warehouse-level recall of nine lots of Pfizer’s [Chantix \(varenicline\)](#) tablets because they 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.
 - Patients taking Chantix who wish to stop should talk to their healthcare provider about other treatment options. Multiple drugs are approved for the same or similar uses as Chantix.
 - FDA recommends health care professionals consider other available treatment options for the patient’s medical condition.
 - N-Nitroso-varenicline belongs to the nitrosamine class of compounds, some of which are classified as probable or possible human carcinogens. Nitrosamines are a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables.
- Chantix is indicated for use as an aid to smoking cessation treatment.
- Pfizer is recalling the Chantix 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.
- The recalled Chantix tablets include the following lots:

Product Description	Lot# (Expiration Date)
Chantix (varenicline)	00020231 (9/30/2021); 00020232 (11/30/2021); 00020357 (12/31/2021); 00020358 (1/31/2022); 00020716 (1/31/2022); 00019213 (1/31/2022); ET1607 (1/31/2023); ET1609 (1/31/2023); EC6994 (5/31/2023)

- Pharmacies with an existing inventory of the recalled product should stop use and quarantine the product immediately.

- FDA is actively considering options to help mitigate a shortage of varenicline in the U.S. including working to identify an alternate supplier.



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