

# UPDATED: Drug Safety Communication: Voluntary Recall of Varenicline (Chantix) Due to Nitrosamine

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August 31, 2021 (Updated September 20, 2021)



Varenicline is a prescription medicine that is used to help adults quit smoking. On September 17, 2021, the U.S. Food and Drug Administration (FDA) announced a voluntary manufacturer recall of all lots of varenicline (Chantix) 0.5 mg and 1 mg tablets due to levels of a nitrosamine impurity, called N-nitroso-varenicline, above the FDA's acceptable intake limit. N-nitroso-varenicline may be associated with a potential increased cancer risk in humans associated with long-term use, but there is no immediate risk to patients taking this medication.

The FDA recommends that patients taking recalled varenicline should continue with their current medication regimen as prescribed, until either their pharmacist provides a replacement, or their doctor prescribes a different medication. The health benefits of stopping smoking outweigh the cancer risk from the nitrosamine impurity in varenicline.

To minimize risk to patients currently taking varenicline, health care professionals should consider the following actions:

- Consider other available treatment options for patients currently taking varenicline.
- Quarantine any varenicline samples and do not provide them to your patients. Contact the manufacturer directly with questions regarding product return or disposal.
- Inform patients who wish to dispose of varenicline to 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 cost reimbursement.
- Report side effects involving varenicline or other medications to the FDA MedWatch program.

The FDA is continuing to investigate the presence of N-nitroso-varenicline in varenicline products and will provide more information as it becomes available. To ensure access to the most recent updates and press announcements, including the full list of recalled lots, refer to ["FDA Updates and Press Announcements on Nitrosamine in Varenicline \(Chantix\)"](#) found on the [Drug Safety and Availability](#) page of the FDA's website.