

### Pfizer – Expansion of recall of Chantix® (varenicline)

- On August 16, 2021, [Pfizer announced](#) an expansion of the voluntary consumer-level recall of [Chantix \(varenicline\)](#) tablets to include four additional lots due to the presence of a nitrosamine, N-nitroso-varenicline, above the Pfizer established acceptable daily intake (ADI) level.
- The additional four recalled lots were distributed from June 2019 to June 2021.

Product Description	NDC#	Lot# (Expiration Date)
Chantix 0.5 mg and 1 mg tablets (carton containing one blister pack of eleven 0.5 mg tablets and one blister pack containing forty-two 1 mg tablets)	0069-0471-03	00018522 (8/2021)
		00018523 (8/2021)
		00018739 (8/2021)
		00018740 (8/2021)

- Chantix is a treatment to help patients quit smoking.
- 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.
- Patients who have the recalled Chantix should contact their healthcare provider if they have experienced any problems that may be related to using the recalled Chantix.
- Anyone with an existing inventory of the recalled product should stop use, distribution and quarantine the product immediately.
- At this time, the [suspended distribution](#) and [shortage](#) of Chantix continues. Pfizer has not announced when they will begin distribution of Chantix. Smoking cessation alternatives, including apo-varenicline, are available.
  - Apotex distributes varenicline in Canada under the name apo-varenicline. [Apotex](#) is coordinating with the FDA to temporarily import apo-varenicline.
- Generic versions of Chantix are not yet available and may launch in the second half of 2021.
- Healthcare providers may contact Pfizer Medical Information at **1-800-438-1985 (option 3)** or Pfizer Drug Safety at **1-800-438-1985 (option 1)** for any questions related to the recall. Patients may contact Stericycle at **1-888-276-6166** for return and replacement information.

- If Chantix was obtained through the Pfizer Patient Assistance program or the Pfizer Institutional Patient Assistance Program, contact **1-833-203-2776** for return and replacement information.



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