Drug Recall: Chantix (varenicline) .5 mg and 1 mg tablets

The FDA has published information that Pfizer is voluntarily recalling all lots of Chantix .5mg and 1 mg tablets due to the presence of nitrosamine, at or above the FDA interim acceptable intake limit.

The following are the affected NDCs:

Drug and Package	NDC Number	Expiration Date
Chantix 0.5 mg tablets, bottle of 56 tablets	00069-0468-56	January 2022 - May 2023
Chantix tablets 1 mg, bottle of 56 tablets	00069-0469-56	September 2021 – December 2023
Chantix tablets 1 mg, carton containing 4 blister packs of 14 tablets each	00069-0469-03	September 2021 – June 2023
Chantix 0.5 mg and 1 mg tablets, carton containing 1 blister pack of 11 0.5 mg tablets and 1 blister pack of 42 1 mg tablets	00069-0471-03	August 2021 – January 2023

Am I at risk?

Long-term ingestion of Nitrosamine may be associated with a theoretical potential increased cancer risk in humans. However, there are no immediate risks to patients taking this medication. Nitrosamines can be found in water and foods, including meats, dairy products, and vegetables. To date, Pfizer has not received reports of adverse events related to this recall.

What should I do?

Patients currently taking Chantix should consult with their healthcare provider about alternative treatment options. For medical questions regarding the product contact Pfizer Medical Information at 1-800-438-1985, option 3 (Mon.-Fri. 9 am-5 pm ET) or www.pfizermedinfo.com

I want to report an adverse reaction

Adverse reactions or quality problems associated with use of this product may be reported to FDA's MedWatch Adverse Event Reporting program through the following:

- Complete and submit the report Online
- Regular Mail or Fax: Download form or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178