

Chantix (Varenicline)

This notice is to inform you that on September 16th, 2021 the U.S. Food and Drug Administration (FDA) announced that Pfizer is voluntarily recalling all lots of Chantix 0.5mg and 1mg tablets due to presence of a nitrosamine, N-Nitroso-varenicline, at or above the FDA interim acceptable intake limit.

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.ⁱ

Chantix is a treatment to help patients quit smoking and is intended for short term use. People who smoke cigarettes are 15 to 30 times more likely to get lung cancer than people who do not smoke.

For any questions related to Pfizer PAP or Pfizer IPAP product, please contact 833-203-2776 (Mon.-Fri. 8:00 am – 6:00 pm ET).