



Dear Healthcare Professional,

Pfizer, in agreement with the Scientific Center of Drug and Medical Technology Expertise after academician Emil Gabrielyan, CJSC, of the Ministry of Health of the Republic of Armenia would like to inform you of important safety information for CHAMPIX (varenicline), which indicated for smoking cessation in adults.

Summary

CHAMPIX (varenicline) batches that were found to contain levels of N-nitroso-varenicline above the acceptable level of intake set at EU level are being recalled in several markets. The recall above to is not applicable to Armenia since the batches were not imported.

Based on the available data, there is no immediate risk to patients currently taking this medication. Since the recall may result in shortages of CHAMPIX in affected markets healthcare professionals are advised to consider the following:

- For patients who are already on CHAMPIX, it may not be possible to complete treatment and healthcare professionals may consider switching treatment to an alternative. Alternatives will vary from market to market but may include nicotine replacement therapy (NRT) and bupropion.
- Healthcare professionals should also take into account the need to consider dose tapering, as the summary of product characteristics (SmPC) states that “At the end of treatment, discontinuation of CHAMPIX was associated with an increase in irritability, urge to smoke, depression, and/or insomnia in up to 3% of patients.”
- Healthcare providers should advise patients undergoing treatment not to discontinue CHAMPIX without consulting them, and to discuss any questions or concerns with their healthcare provider if needed.

Background on the safety concern

Pfizer tested CHAMPIX product lots for the presence of the CHAMPIX-derived nitrosamine, N-nitroso-varenicline. Test results indicated levels of N-nitroso-varenicline in certain lots exceeded the Pfizer product-specific acceptable daily intake (ADI) level. N-nitroso-varenicline is a nitrosamine. Nitrosamines are classified as probable human carcinogens (substances that could cause cancer). Nitrosamines can be found at very low levels in water and foods, including cured and grilled meats, dairy products and vegetables. Nitrosamine impurities may increase the risk of cancer if people are exposed to them above acceptable levels over long periods of time. Upon request from EMA’s (European Medicines Agency) human medicines committee, CHMP, Pfizer is recalling product lots above the acceptable intake level.

Based on Pfizer’s safety assessment the benefit/risk of varenicline remains positive. There is no evidence that short term use of CHAMPIX, in line with the authorized indication and as typically prescribed, leads to risk to patients.

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Call for reporting

Suspected adverse effects reports can be provided for medicinal products in postmarketing stage. This allows to continuously assess the benefit/risk profile of the product. Healthcare professionals can report any suspected adverse reactions to Scientific Center of Drug and Medical Technology Expertise after academician Emil Gabrielyan, CJSC, of the Ministry of Health of the Republic of Armenia online at www.pharm.am, via e-mail vigilance@pharm.am or call the hotline (+374 10) 20-05-05, (+374 96) 22-05-05.

Company contact point

Healthcare professionals are also encouraged to report any suspected adverse reactions to Pfizer at +74952875000.

If you have any questions or would like additional information, please call Pfizer Medical Information at +74952875000.

A handwritten signature in blue ink, appearing to read 'T. Prokhorova', written over a horizontal line.

Yours faithfully,

Tatyana Prokhorova, MD, PhD,

Pfizer Eurasian Economic Union Qualified Person for Pharmacovigilance