Ref: 09/2021/PLD
23/09/2021

Direct Healthcare Professional Communication

CHAMPIX (varenicline) - lots to be recalled due to presence of impurity N-nitroso-varenicline above the acceptable intake limit

Dear Healthcare Professional,

Pfizer, in agreement with the European Medicines Agency and the Malta Medicines Authority would like to inform you of the following:

Summary

- **All 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.**
- **Based on the available data, there is no immediate risk to patients currently taking this medication.**
- **The recall will result in further shortages of CHAMPIX (earlier recall of several batches took place in July 2021).**
- **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 professionals should advise patients undergoing treatment not to discontinue CHAMPIX without consulting them, and to discuss any questions or concerns with their healthcare professionals if needed.**

Background on the safety concern

CHAMPIX (varenicline) is indicated for smoking cessation in adults.

Test results have identified the levels of N-nitroso-varenicline in Champix to exceed the acceptable intake (AI) 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 human medicines committee, CHMP, Pfizer is recalling product lots above the AI level.

Call for reporting

Healthcare professionals are reminded to continue to report suspected adverse reactions associated with CHAMPIX in accordance with the National spontaneous reporting system.

Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and sent to ADR reporting/Post-Licensing Directorate/Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann, Malta, or sent by email to: postlicensing.medicinesauthority@gov.mt

Healthcare professionals are asked to report any suspected adverse reactions.

Company contact point

Should you have any questions or require additional information, please contact Vivian Corporation Limited at:

Company	Product Name	Website	Phone
Pfizer Hellas S.A. Local Representative: Vivian Corporation Ltd.	CHAMPIX 0.5 mg and 1 mg film-coated tablets	https://www.pfizer.com/products/product-contact-information	+00356 22588600

Yours faithfully,

Post-Licensing Directorate

Medicines Authority

Disclaimer

This Direct Healthcare Professional Communication has been submitted to you on behalf of Pfizer Hellas S.A. and the local agent Vivian Corporation Limited.