Varenicline:
Summary of Product Characteristics and Package Leaflet update

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Varenicline (Champix) is not currently available because of production issues. See the Clinical tools section of our website for further information:
www.ncsct.co.uk/pub_clinical-tools.php

CHAMPIX® (varenicline) Summary of Product Characteristics (SmPC) and Package Leaflet **now updated to Include New Safety & Efficacy Data from the EAGLES Clinical Trial Following Positive Opinion by CHMP**[1]

- ✓ *Latest scientific evidence supports HCPs, commissioners and providers of smoking cessation services when considering varenicline (Champix) as a treatment option for smokers who want to quit*[2]
- ✓ *The Black triangle* symbol ▼ which is used on medicines to indicate that *additional safety monitoring is required for a medicine in the UK has been removed by the EMA from varenicline (Champix)*[1]

Detail

- **About EAGLES the Trial:**[2] The Evaluating Adverse Events in a Global Smoking Cessation Study (EAGLES) is the **first and largest randomised, double-blind, placebo-controlled clinical study of approved smoking cessation medicines to date,** including 8,144 adult smokers with and without a history of psychiatric disorder. EAGLES was conducted at the request of, and designed in consultation with, the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). By design, **half (4,116) of the study participants had a history of psychiatric disorder.**

  The EAGLES study was primarily designed to evaluate the neuropsychiatric safety of varenicline and bupropion, compared to placebo, in adult smokers with and without a history of psychiatric disorder. The primary safety endpoint was a composite endpoint defined as the occurrence of at least one treatment-emergent severe adverse event of anxiety, depression, feeling abnormal, or hostility and/or the occurrence of at least one treatment-emergent moderate or severe adverse event of agitation, aggression, delusions, hallucinations, homicidal ideation, mania, panic, paranoia, psychosis, suicidal ideation, suicidal behaviour, or completed suicide.

  The results suggest that **varenicline and bupropion do not significantly increase the risk of neuropsychiatric adverse events** in the primary composite endpoint, as compared to placebo or nicotine patch (Niquitin), **in patients with or without a history of psychiatric disorder.**

  Across the trial population, the most frequent adverse event by treatment group was nausea (25%, varenicline), insomnia (12%, bupropion), abnormal dreams (12%, nicotine patch), and headache (10%, placebo).

  The safety and tolerability of varenicline in this study is in line with that seen in other clinical trials.

- The results from the trial demonstrated that the use of varenicline or bupropion in patients with or without a history of psychiatric disorder were not associated with a significantly increased risk of serious neuropsychiatric adverse events compared with placebo.[2] In addition, **patients taking arenicline in EAGLES showed statistically superior continuous abstinence rates with Champix at weeks 9 – 12 and 9 – 24 compared with patients treated with placebo, bupropion or nicotine (Niquitin) patch.**[2] The outcomes of the EAGLES trial were recently published in The Lancet.[2]

- Professor Robert West, Professor of Health Psychology, University College London and co-author of the EAGLES study commented, *"Smoking remains a major public health challenge in the UK, with millions continuing to smoke despite it being the number one cause of preventable death. For those who are serious about quitting, healthcare professionals are best placed to offer them the support and most appropriate treatment option to help them, based on the growing body of scientific evidence. The results from EAGLES and the varenicline label update should further reassure doctors and patients about the safety and effectiveness of medicines to help smokers to stop."*
- The European Summary of Product Characteristics (SmPC) and Package Leaflet for varenicline have been updated to include safety and efficacy data from the EAGLES (**E**valuating **A**dverse Events in a **Gl**obal Smoking C**e**ssation **S**tudy) trial.[1]
- As part of the update, the black triangle symbol ▼, which is used to indicate that additional safety monitoring for medicines in the UK is required, has been removed.[1]
- The varenicline Summary of Product Characteristics (SmPC) and Package Leaflet update was implemented following adoption of a positive opinion by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency and completion of the linguistic review.
- The Warnings and Precautions in the Champix label now state that the use of varenicline in patients with or without a history of psychiatric disorder was not associated with an increased risk of serious neuropsychiatric adverse events compared with placebo. Depressed mood, rarely including suicidal ideation and suicide attempt, may be a symptom of nicotine withdrawal. Clinicians should be aware of the possible emergence of serious neuropsychiatric symptoms in smokers attempting to quit with or without treatment. If serious neuropsychiatric symptoms occur whilst on varenicline treatment, patients should discontinue varenicline immediately and contact a healthcare professional for re-evaluation of treatment. Care should be taken with patients with a history of psychiatric illness and patients should be advised accordingly.
- Link to varenicline (Champix®) prescribing information: www.medicines.org.uk/emc/medicine/19045

References

1. Champix® (varenicline): EU Summary of Product Characteristics. Pfizer.

2. Anthenelli RM, Benowitz NL, West R, et al. Neuropsychiatric safety and efficacy of varenicline, bupropion, and nicotine patch in smokers with and without psychiatric disorders (EAGLES): a double-blind, randomized, placebo-controlled clinical trial. *Lancet*. 2016 Apr 19:e1-e14. [Epub ahead of print].