

AIFA – Agenzia Italiana del Farmaco

Vareniclina. Avviso di sicurezza TGA su rischi di sintomi psichiatrici e potenziali interazioni con l'alcol

04 Dicembre 2015

L'australiana TGA (Therapeutic Good of Health) ha comunicato ai pazienti e agli operatori sanitari di aver aggiornato le Product Information (PI) del farmaco Champix (vareniclina), con nuove informazioni di sicurezza che riguardano i rischi di sintomi psichiatrici e potenziale interazione con l'alcol. I sintomi psichiatrici possono comportare cambiamenti nel comportamento, nei pensieri o nell'umore e includere depressione, ansia, agitazione, aggressività, sbalzi d'umore, autolesionismo o allucinazioni.

Vareniclina è un agonista parziale del recettore nicotinico dell'acetilcolina e viene utilizzato negli adulti per aiutarli a smettere di fumare e ad alleviare i sintomi del desiderio compulsivo e dell'astinenza associati alla cessazione dell'abitudine al fumo. Le Product Information (PI) aggiornate – scrive l'Agenzia australiana – mirano ad aumentare la consapevolezza sui gravi sintomi psichiatrici riportati in pazienti che assumevano vareniclina e a sottolineare l'importanza di interrompere il trattamento con vareniclina e contattare un professionista sanitario se si presentano o si osservano tali sintomi.

La TGA raccomanda agli operatori sanitari di discutere con il paziente prima di prescrivere il farmaco i benefici e i rischi del trattamento con vareniclina, inclusi i potenziali sintomi psichiatrici.

Le informazioni di cui sopra erano già presenti nelle precedenti PI, ma sono ora elencate in grassetto all'inizio della sezione Precauzioni, sotto il titolo "I sintomi psichiatrici", per rafforzare questi importanti messaggi.

Le sezioni "Precauzioni, interazioni con altri medicinali ed effetti avversi" delle PI sono state aggiornate anche sulla necessità di avvertire i pazienti che il consumo di alcol può aumentare il rischio di sintomi psichiatrici.

La TGA osserva che vi sono anche una serie di altri fattori che possono contribuire ai sintomi psichiatrici segnalati in relazione al trattamento con vareniclina, compresi gli effetti da sospensione della nicotina, malattie psichiatriche e l'uso di alcuni altri farmaci.

TGA – Therapeutic Goods Administration

Varenicline (Champix)

Safety advisory – risks of psychiatric symptoms and potential interaction with alcohol

2 December 2015

Consumers and health professionals are advised that the Product Information (PI) for varenicline, marketed in Australia as Champix, has recently been updated with new safety information.

This information relates to the risks of psychiatric symptoms and potential interaction with alcohol. Psychiatric symptoms can involve changes in behaviour, thinking or mood and may include depression, anxiety, agitation, aggression, mood swings, self-harm, thoughts of self-harm, or seeing, hearing or sensing things that are not there.

Varenicline is a prescription medicine that assists adults to stop smoking by helping to reduce nicotine cravings and withdrawal symptoms. Smoking is associated with serious health problems that can lead to death.

The updated PI aims to:

- increase awareness that serious psychiatric symptoms have been reported in patients taking varenicline
- stress the importance of stopping treatment with varenicline and immediately contacting a health professional if these symptoms are experienced or observed.

Health professionals should discuss the benefits and risks of treatment with varenicline, including potential psychiatric symptoms, before prescribing this medicine.

The above information was previously provided in the PI, but is now listed in bold text at the beginning of the Precautions section, under the heading 'Psychiatric Symptoms', to reinforce these important messages.

The Precautions, Interactions With Other Medicines and Adverse Effects sections of the PI have also been updated regarding the need to advise patients that consuming alcohol may increase the risk of psychiatric symptoms.

It is noted that there are a number of other factors that can also contribute to psychiatric symptoms being reported in relation to treatment with varenicline, including the effects of nicotine withdrawal, existing psychiatric conditions and use of some other medicines.

The updated PI also includes information from clinical trials and observational studies, which found similar incidence rates of suicidal thoughts and/or behaviour, as well as other common psychiatric symptoms, in patients treated with varenicline as to those treated with placebo or alternative treatments.

The TGA will continue to monitor this issue.

Information for consumers

If you or someone you care for is taking varenicline, be aware of the risks of psychiatric symptoms and potential interaction with alcohol.

If you suspect any psychiatric symptoms, such as depression, anxiety, agitation, aggression, mood swings, self-harm, thoughts of self-harm, or seeing, hearing or sensing things that are not there, during treatment with this medicine, stop taking it and contact a health professional immediately.

If you have any questions or concerns regarding this issue, speak to your health professional.

Information for health professionals

Please be aware of the above information and refer to the PI for further details.

You should discuss the benefits and risks of varenicline treatment, including potential interaction with alcohol, with patients who are taking, or for whom you may prescribe, this medicine.

Reporting problems

Consumers and health professionals are encouraged to report problems with medicines or vaccines. Your report will contribute to the TGA's monitoring of these products.

The TGA cannot give advice about an individual's medical condition. You are strongly encouraged to talk with a health professional if you are concerned about a possible adverse event associated with a medicine or vaccine.