IRISH MEDICINES BOARD

Champix (varenicline)

Champix is a medicinal product authorised for use throughout the European Union since December 2006 through the European licensing process for the treatment of smoking cessation in adults. It contains varenicline, a non-nicotine aid which acts as a partial agonist at the nicotinic $\alpha 4\beta 2$ receptor and so can help reduce the cravings and withdrawal symptoms associated with stopping smoking. The dose of varenicline should be carefully titrated in accordance with the licensed recommendations, with lowering of the dose for patients who cannot tolerate the adverse effects, either temporarily or for the duration of treatment (See Summary of Product Characteristics (SmPC) for full prescribing information).

Since it was first authorised, the IMB, in conjunction with the European Medicines Agency (EMA), has closely monitored the safety of varenicline. Frequently reported adverse reactions notified in association with its use include gastrointestinal disorders (such as increased appetite, nausea, vomiting and taste disturbance), general effects such as fatigue and CNS effects such as headache, somnolence, dizziness and sleep disorders (including insomnia and abnormal dreams). It is important to note that these suspected reactions may not necessarily have been caused by varenicline and may relate to other factors including nicotine withdrawal, other illnesses, or other medications taken concurrently by the patient. For a complete list of side effects associated with varenicline use, please see the SmPC.

Depression, suicidal ideation/behaviour and psychosis have also been reported in patients treated with varenicline. Not all patients had stopped smoking at the time of onset of symptoms and not all patients were reported as having pre-existing psychiatric illness. Following concerns about reports of neuropsychiatric conditions associated with the use of varenicline, the available data were reviewed at EU level. As previously communicated by the IMB, this review concluded that smoking cessation, with or without treatment may be associated with symptoms such as irritability, anxiety, depression (rarely including suicidal ideation), and may also exacerbate an underlying psychiatric condition. The product information for varenicline was updated to include additional warnings about the risk of depression, associated with its use and as a symptom of nicotine withdrawal. It was also recommended that patients should be advised accordingly.

The safety and efficacy of varenicline in patients with serious psychiatric illness such as schizophrenia, bipolar disorder and major depressive disorder have not been established. Care should be taken with patients with a history of psychiatric illness, alternative therapeutic options should be considered and patients should be advised of the risk of neuropsychiatric events.

Healthcare professionals are reminded to adhere to the approved recommendations for use of varenicline and to highlight to those taking varenicline the possibility of psychiatric adverse effects. Patients should be closely monitored during use and advised to report any symptoms associated with their treatment to their doctor. Varenicline should be discontinued immediately if agitation, depressed mood or changes in behaviour or thinking that are of concern for the doctor, the patient, family or caregivers are observed, or if the patient develops suicidal ideation or suicidal behaviour. Ongoing follow up should be provided until the symptoms resolve.

The IMB is continuing to closely monitor experience with use of varenicline in Ireland, particularly in relation to cases of neuropsychiatric symptoms that have been reported. All suspected adverse reactions associated with use of varenicline should be notified to the IMB in the usual way.

Advice for healthcare professionals:

- Varenicline should be used in accordance with the licensed prescribing instructions.
- Patients should be advised of the possibility of psychiatric adverse effects when taking varenicline and to contact their doctor immediately if they develop suicidal thoughts or behaviour.
- Patients should be closely monitored during use of varenicline and it should be discontinued immediately if agitation, depressed mood, or changes in behaviour are observed that are of concern for the doctor, patient, family, or caregiver.

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