



21st June 2011

Varenicline 0.5 mg and 1 mg tablets (Champix® ▼)

The New Therapies Subgroup discussed the above drug at a meeting on the 21st June 2011. The recommendation of this subgroup is as follows:*

The New Therapies Subgroup of the GMMMG considered varenicline for its licensed indication of smoking cessation in adults.

The group recommends that varenicline is considered as an option for use only after an adequate trial of nicotine replacement therapy (when used as part of a managed programme) has failed or is contraindicated.

If varenicline is considered appropriate for prescribing it must only be prescribed alongside specialist support as part of a smoking cessation service.

The group considered the high placebo effect seen in trials and the high levels of motivational support offered to trial participants to be an important consideration in their decision. They also noted the absence of data on efficacy or safety of varenicline in patients with significant co-morbidities. **In particular, caution is necessary in patients with a previous history of psychiatric illness including depression, because depression and suicidal thoughts and behaviour have been reported in patients treated with varenicline.**

Recent data (June 2011) also suggests that varenicline may be associated with a small but increased risk of certain cardiovascular adverse events in patients who have cardiovascular disease however the European Medicines Agency has confirmed that the benefit-risk balance for varenicline (Champix®) remains positive, despite the results of a recent meta-analysis of the medicine's side effects affecting the heart and blood vessels.

Review date: June 2013

* Unless superseded by NICE guidance or substantial and significant new evidence becomes available.

▼ Newly marketed drugs and vaccines are intensively monitored for a minimum of two years, in order to confirm the risk / benefit profile of the product. Healthcare professionals are encouraged to report all suspected adverse drug reactions regardless of the severity of the reaction.