

Results of the Experience With the Use of Varenicline in Daily Practice Using Intensive Monitoring

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Background: Although a concise overview of Adverse Drug Reactions (ADRs) of varenicline is known, little is known about the time related information about ADRs of varenicline such as for example latencies. **Objectives:** To gain insight in the experience and safety of varenicline in daily practice as reported by patients through web-based questionnaires using an intensive monitoring system.

Methods: A prospective, observational, non-interventional cohort study was conducted. First-time users of varenicline were defined as patients who have not filled in a prescription of varenicline in the previous 12 months using the first prescription signal in that particular pharmacy. All first-time users of varenicline in participating pharmacies between 1 December 2008 and 31 March 2012 were invited for the study. Patients could sign up for the study on a dedicated website. Electronic questionnaires were sent after 1, 2 and 6 weeks, 3 months and 4 months after they started to use varenicline. In these questionnaires questions about drug use and ADRs were asked for. The main outcome was information about the ADR, seriousness, and action taken when experiencing an ADR. Descriptive analysis was done using Microsoft Access.

Results: 1418 patients signed up for the study. Response rates for the various questionnaires vary from 31.3 to 62.5 %. 58.8 % of the patients reported at least one ADR. The most frequently reported ADRs were nausea (30.8 %), abdominal pain (11.2 %) and abnormal dreaming (10.3 %) which are listed in the Summary of Product Characteristics of varenicline (SmPC). Median latency times were 3–7 days, with exception for depressed mood (10 days). The number of ADRs did not abate over time. No signals were detected. During treatment 43.9 % of the patients stopped using varenicline. The main reasons for stopping were the occurrence of ADRs (42.2 %) and other (40.0 %) unspecified reasons.

Conclusions: This study indicates that varenicline is a relatively safe drug. The reported ADRs correspond with the ADRs mentioned in the SmPC of varenicline with a median latency of 3–7 days. The number of ADRs do not abate over time.

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