

## 15 Safety Profile of Modafinil Used in General Practice in England: A Modified Prescription Event Monitoring Study

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**Background:** Since April 2004 modafinil has been indicated for the relief of excessive sleepiness associated with chronic pathological conditions, including narcolepsy, obstructive sleep apnoea/hypopnoea syndrome (OSAHS), and shift work sleep disorder (SWSD). In May 2006 the term chronic pathological conditions was removed.

**Objectives:** To monitor the safety of modafinil prescribed in primary care in England using Modified Prescription Event Monitoring (PEM).

**Methods:** An observational cohort study; patients identified from dispensed prescriptions issued by general practitioners (GPs) from July 04-Aug 05. Demographic/clinical event data were collected from questionnaires posted to GPs at least 6 months after the 1<sup>st</sup> prescription date. Statistical analysis to determine the incidence density (ID) in the 1st month (ID<sub>1</sub>), and months two to six (ID<sub>2-6</sub>) was carried out. Follow-up and causality assessment of medically significant events was undertaken.

**Results:** 2416 (60.1%) of the 4023 questionnaires posted were returned. Results pertain to 1096 patients who had prescriptions issued after April 2004 (corresponding with the change of licence). 497 (45.3%) males, 599 (54.7%) females. The main indications were narcolepsy (268, 24.5%), lassitude (265, 24.2%) and multiple sclerosis (147, 13.4%). Modafinil was stopped in 309 (28.2%) patients. The most frequent reason for stopping was not effective (111, 10.1%); the most common event was headache (11, 1.0 %). 27 events were reported as suspected ADRs in 17 (1.6%) patients. The most frequent ADRs were headache, dizziness and visual disturbance. For the indication of narcolepsy, the events with the highest ID<sub>1</sub> were dyspnoea, headache and micturition disorder, for the indication of OSAHS they were euphoria, headache and visual defect. One patient reportedly abused modafinil. 12 women took modafinil during their pregnancy; no congenital abnormalities were reported.

**Conclusions:** The adverse events listed above are included in the current SPC, with the exception of euphoria

**Conflicts of interest:** The DSRU, a registered independent charity (No. 327206) which works in association with the University of Portsmouth, has received unconditional donations from the manufacturer of modafinil.