The pharmacovigilance of mirtazapine: results of a prescription event monitoring study on 13 554 patients in England

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Abstract

Mirtazpine is the first noradrenaline and serotonin specific antidepressant. We monitored the safety of mirtazapine as reported in primary practice in England.The exposure data were provided by monitoring the dispensed prescriptions issued between September 1997 and February 1999. Questionnaires sent to GPs provided outcome data. Drowsiness/sedation and malaise/lassitude were the most frequent ADRs (116, 71 respectively) and had the highest incidence density (per 1000 patient-months) in the first month of treatment (58.1, 27.8 respectively). Agitation (73), aggression (70), rash (20),

hallucinations (13) and abnormal dreams (31 were unlabelled AES while abnormal liver function tests (12), syncope (8), abnormal behaviour (4) and visual disturbance (3) were labelled AES possibly due to mirtazapine use. Serious suspected ADRs reported were facial oedema (5), allergy (3), bone marrow toxicity (2) and myelodysplasia (1).

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