
RESULTS OF THE NON-INTERVENTIONAL STUDY VIVRE: TREATMENT EFFECT OF AGOMELATINE ON DEPRESSIVE SYMPTOMS, ANXIETY SYMPTOMS WITHIN DEPRESSION AND SOCIAL AND EMOTIONAL FUNCTIONING OVER 3 MONTHS

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Introduction: Agomelatine, a melatonergic agonist and 5-HT_{2c}-antagonist, has demonstrated antidepressant efficacy in clinical trials.

Aims: Aim of VIVRE was to document treatment with agomelatine non-interventionally in daily-practice over 3 months.

Objectives: Evaluation of the effectiveness of agomelatine on depressive symptoms, anxiety symptoms within depression, social functioning and tolerability in naturalistic setting.

Methods: 1891 outpatients aged >18 years treated with agomelatine 25-50mg once daily were observed by 616 German psychiatrists and specialized practitioners over 3 months. Antidepressant effectiveness was evaluated by Clinical-Global-Impression (CGI) by doctors and Patient-Global-Impression (PGI) by patients, effects on social functioning by Sheehan-Disability-Scale (SDS), anxiety symptoms within depression by COVI-Anxiety-Scale (COVI). ADRs were documented at every visit.

Results: According to CGI, 30.3% had responded after 2 weeks, 82.1% at study-end (CGI-I≤2), and 39.9% were classified as remitters (CGI-S≤2) by physicians after 3 months. Anxiety symptoms within depression (total score) improved in 92.9% of patients. Patients documented response (PGI-I≤2) in 16.4% after 2 weeks and 73.1% at study-end, remission (PGI-C≤2) in 47.6% after 12 weeks. SDS-total-score decreased from 20.4 at baseline to 7.7 after 12 weeks corresponding improvement of functional impairment for 94.5% of patients. Improvement in domains work/school, social life and family-life/home were observed for 91.8%, 91.1% and 91.9% respectively. Adverse drug reactions (mainly headache, nausea, dizziness) were reported for 2.6% of patients, in 0.5% (n=10) ALT/AST>3ULN were documented.

Conclusion: Antidepressant effectiveness of agomelatine, improvement of anxiety symptoms within depression as well as social and emotional functioning and good tolerability were observed in daily-practice over 3 months.