

**Effectiveness and Tolerability of the Antidepressant Agomelatine in Daily Practice in Germany: Meta-analysis of 4 Non-interventional Studies**

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**Introduction:** Agomelatine, a melatonergic agonist and 5-HT<sub>2c</sub>-antagonist, has demonstrated antidepressant efficacy and safety in clinical trials.

**Aim/Objectives:** Metaanalysis of non-interventional-studies of agomelatine-treatment in depression to evaluate tolerability and antidepressant effectiveness of agomelatine under routine conditions in a large patient-population in Germany.

**Methods:** Pooled data-analysis from 4 non-interventional-studies (2009-2013). 9601 outpatients aged >18 years were observed by 2770 psychiatrists and general practitioners in Germany. Analysis was performed after 12 weeks (W12) and after 24/52 weeks (W24/W52) of treatment with agomelatine 25-50mg once daily. Antidepressant effectiveness was evaluated by Clinical-Global-Impression-Severity/Improvement (CGI-S/I). Liver-function-tests (LFT) were documented as available, ADRs at every visit.

**Results:** Baseline CGI-S mean-value (4.7) improved over 12/24/52 weeks of treatment with agomelatine (to 3.0/2.8/2.6), corresponding improvement in 81%/82%/87% of patients. According to CGI-I, 24.3% responded (CGI-I≤2) after 2 weeks, 63.0% (W6), 87.7% (W12), 79.3% (W24) and 81.7% (W52). 34.5% of patients were classified as remitters (CGI-S=1 or 2) after 12 weeks, 38.1% (W24) and 47.5% (W52). Adverse drug reactions (mainly headache, nausea, dizziness) were reported for 5.32% (W12), 0.49% (W12-W24) and 0.99% (W24-M12) of patients, sADR in 0.2%/0.05%/0%. 49 patients (0.5%) had ALT/AST>3ULN (W0-W13), thereof 19 patients with preexisting transaminase-elevations at baseline. One patient with reversible hepatitis was documented (W10-W17), treatment was stopped. All other patients were without clinical symptoms. Mean weight (76.9 vs 77.0kg) and BMI (26.4 vs 26.5) remained unchanged.

**Conclusion:** This metaanalysis documents good tolerability of agomelatine and antidepressant effectiveness in a large population of unselected patients in German daily practice over 3, 6 and 12 months.