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LONG-TERM EFFICACY AND SAFETY OF ZOLPIDEM EXTENDED-RELEASE 12.5 MG, IN OLD PATIENTS WITH CHRONIC PRIMARY INSOMNIA: A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PARALLEL-GROUP, MULTICENTER STUDY

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Objective: To evaluate long-term efficacy and safety of zolpidem extended-release, in old patients for chronic primary insomnia.

Design: Multicenter, randomized, double-blind, placebo-controlled, parallel-group.

Method: Population: Outpatient with aged more of 65 years. Diagnosis: DSM-IV criteria for chronic primary insomnia; Treatment: Single-dose zolpidem extended-release 12.5 mg (n = 128) or placebo (n = 127), self-administered every night.

Results: Patient's Global Impression (PGI) and Clinical Global Impression-Improvement (CGI-I) were assessed every 4 weeks up to six month. Patient Morning Questionnaire (PMQ), recorded daily, assessed subjective sleep measures-sleep onset latency (SOL), total sleep time (TST), number of awakenings (NAW), wake time after sleep onset (WASO), and quality of sleep (QOS)-and next-day functioning. Zolpidem extended-release also was statistically significantly superior to placebo at every time point for PGI (Items 1-4) and CGI-I ($P < 0.0001$, rank score), TST, WASO, QOS ($P < 0.0001$), and SOL ($P < \text{or} = 0.0014$); NAW (Months 2-6; $P < 0.0001$). Sustained improvement ($P < 0.0001$, all time points) was observed in morning sleepiness and ability to concentrate ($P = 0.0014$, month 6) with zolpidem extended-release compared with placebo. Most frequent adverse events for zolpidem extended-release were headache, anxiety and somnolence to the morning. No rebound effect was observed during the first 3 nights of discontinuation.

Conclusions: These findings establish the efficacy of dosing of zolpidem extended-release 12.5 mg for up to 6 months. Treatment provided sustained and significant improvements in sleep onset and maintenance and also improved next-day concentration and morning sleepiness.