

EFFICACY AND SAFETY OF VARDENAFIL ORODISPERSIBLE TABLET FOR THE TREATMENT OF ERECTILE DYSFUNCTION IN ELDERLY MEN AND THOSE WITH UNDERLYING CONDITIONS

G.A. Dijkman¹, H. Sperling², M. Gittelman³, C. Norenberg⁴,
E. Ulbrich⁵, S. Ewald⁴

¹*Andros Mannenkliniek, Maastricht, The Netherlands*

²*Kliniken Maria Hilf GmbH, Mönchengladbach, Germany*

³*Department of Urology, South Florida Medical Research, Aventura, FL, USA*

⁴*Bayer HealthCare AG, Wuppertal, Germany*

⁵*Bayer Vital GmbH, Leverkusen, Germany*

Aim: To examine the efficacy and safety of vardenafil orodispersible tablet (ODT) for the treatment of erectile dysfunction (ED).

Methods: This integrated analysis of two phase III, double-blind, multicentre, randomised, parallel-group, placebo-controlled studies compared 10 mg on-demand vardenafil ODT with placebo in a general population of men with ED, where 51% were aged ≥ 65 years. Results were reported by age (<65 vs ≥ 65 years), baseline ED severity (mild, moderate, severe) and presence/absence of diabetes, dyslipidemia or hypertension. Primary efficacy measures: International Index of Erectile Function, erectile function domain (IIEF-EF) and Sexual Encounter Profile questions 2 and 3 (SEP2/3).

Results: Of 701 randomised men, 686 comprised the intent-to-treat population (placebo, n=334; vardenafil ODT, n=352). Vardenafil ODT was significantly superior to placebo for all primary measures, regardless of age, ED severity or underlying conditions (all $p < 0.0001$). IIEF-EF scores and SEP2/3 success rates were comparable between older/younger men, and men with/without underlying conditions. Least squares mean IIEF-EF scores for vardenafil ODT vs placebo (week 12/last observation carried forward|baseline) were: <65 years 22.7|13.0 vs 14.7|13.3, ≥ 65 years 19.6|11.7 vs 13.5|12.4; with diabetes 19.3|11.5 vs 13.9|11.6, without diabetes 21.8|12.7 vs 14.1|13.2; with dyslipidemia 19.8|12.6 vs 13.3|12.7, without dyslipidemia 21.9|12.2 vs 14.4|12.9; with hypertension 20.3|12.1 vs 13.4|11.9, without hypertension 21.6|12.5 vs 14.6|13.5. Adverse events (AEs) were mostly mild to moderate in severity. The most common vardenafil ODT-related AEs were headache, flushing, nasal congestion, dizziness and dyspepsia.

Conclusions: Vardenafil ODT significantly improves erectile function in men with ED, regardless of age, ED severity or underlying condition.