

**THE EFFECT OF MAINTENANCE TREATMENT
WITH ERDOSTEINE ON EXACERBATION TREATMENT
AND HEALTH STATUS IN PATIENTS WITH COPD:
A POST-HOC ANALYSIS OF THE RESTORE DATASET**

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Aim: To explore the effect of erdoesteine on COPD exacerbations, health-related quality of life (HRQoL), and subjectively assessed COPD severity.

Patients and methods: This post-hoc analysis of the RESTORE study included participants with COPD and spirometrically moderate (GOLD 2; post-bronchodilator forced expiratory volume in 1 second [FEV1] 50–79 % predicted; n = 254), or severe airflow limitation (GOLD 3; post-bronchodilator FEV1 30–49 % predicted; n = 191) who received erdoesteine 300 mg twice daily or placebo added to usual maintenance therapy for 12 months. Antibiotic and oral corticosteroid use was determined together with patient-reported HRQoL (St George's Respiratory Questionnaire, SGRQ). Patient and physician subjective COPD severity scores (scale 0–4) were rated at baseline, 6 and 12 months. Data were analyzed using descriptive statistics for exacerbation severity, COPD severity, and treatment group. Comparisons between treatment groups used Student's t-tests or ANCOVA as appropriate.

Results: Among GOLD 2 patients, 43 of 126 erdoesteine-treated patients exacerbated (7 moderate-to-severe exacerbations), compared to 62 of 128 placebo-treated patients (14 moderate-to-severe exacerbations). Among those with moderate-to-severe exacerbations, erdoesteine-treated patients had a shorter mean duration of corticosteroid treatment (11.4 days vs 13.3 days for placebo, $P = 0.043$), and fewer patients required antibiotic treatment with/without oral corticosteroids (71.4% vs 85.8% for placebo, $P < 0.001$). Erdoesteine-treated GOLD 2 patients who exacerbated showed significant improvements from baseline in SGRQ total scores and subjective disease severity scores (patient- and physician-rated), compared with placebo-treated patients regardless of exacerbation severity. Among GOLD 3 patients, there were no significant differences between treatment groups on any of these measures.

Conclusion: Adding erdoesteine to the usual maintenance therapy of COPD patients with moderate airflow limitation reduced the number of exacerbations, the duration of treatment with corticosteroids and the episodes requiring treatment with antibiotics. Additionally, treatment with erdoesteine improved HRQoL and patient-reported disease severity.

Keywords: antibiotic, chronic obstructive pulmonary disease, erdoesteine, COPD exacerbation, health-related quality of life, systemic corticosteroid.