

**Abstract N°: 6626****Effects of oral roflumilast therapy on body weight and cardiometabolic parameters in patients with psoriasis – findings from the PSORRO study**

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**Title:**

Effects of oral roflumilast therapy on body weight and cardiometabolic parameters in patients with psoriasis – findings from the PSORRO study

**Introduction & Objectives:**

Oral roflumilast, a phosphodiesterase (PDE)-4 inhibitor approved for chronic obstructive pulmonary disease, has weight loss as a frequently reported side effect. Recently, oral roflumilast has shown efficacy in the treatment of psoriasis, a disease strongly linked to overweight/obesity. The aim was to examine the effects of oral roflumilast on body weight and cardiometabolic parameters in patients with moderate-to-severe psoriasis.

**Materials & Methods:**

Patients\*\* with plaque psoriasis were randomized 1:1 to oral roflumilast 500 µg once-daily or placebo for 12 weeks, followed by active, open-label treatment through week 24 in both groups. Changes in body weight, blood pressure, gastrointestinal symptoms, and laboratory tests were registered. No lifestyle or dietary interventions were applied. Outcomes were evaluated based on intention-to-treat and tested with Fisher's exact tests (binary outcomes) and Mann-Whitney U tests (numeric variables). Missing data were handled with non-responder imputations for binary outcomes and last observation carried forward (LOCF) for numeric outcomes.

**Results:**

Forty-six patients were randomized. Baseline characteristics across groups were comparable. In the active treatment arm, mean body weight was 102.0 kg (BMI 33.3 kg/m<sup>2</sup>); in the placebo arm, mean body weight was 105.1 kg (BMI 32.2 kg/m<sup>2</sup>). A total of 13% and 9% of patients in the roflumilast and placebo group, respectively, had type 2 diabetes. In patients receiving roflumilast, median weight change was -2.6% and

-4% at week 12 and 24, respectively. Corresponding numbers were 0.0% and -1.3% in patients initially allocated to placebo. During the 24-week study, a total of 57%, 30%, 17%, and 13% of patients treated with roflumilast since randomization lost ≥3%, ≥5%, ≥10%, and ≥15%, respectively, of their baseline body weight. Reduced appetite was more frequent with active therapy. No changes in blood pressure or laboratory tests were observed. No patients received bariatric surgery or body weight-lowering medications before or during the trial.

**Conclusion:**

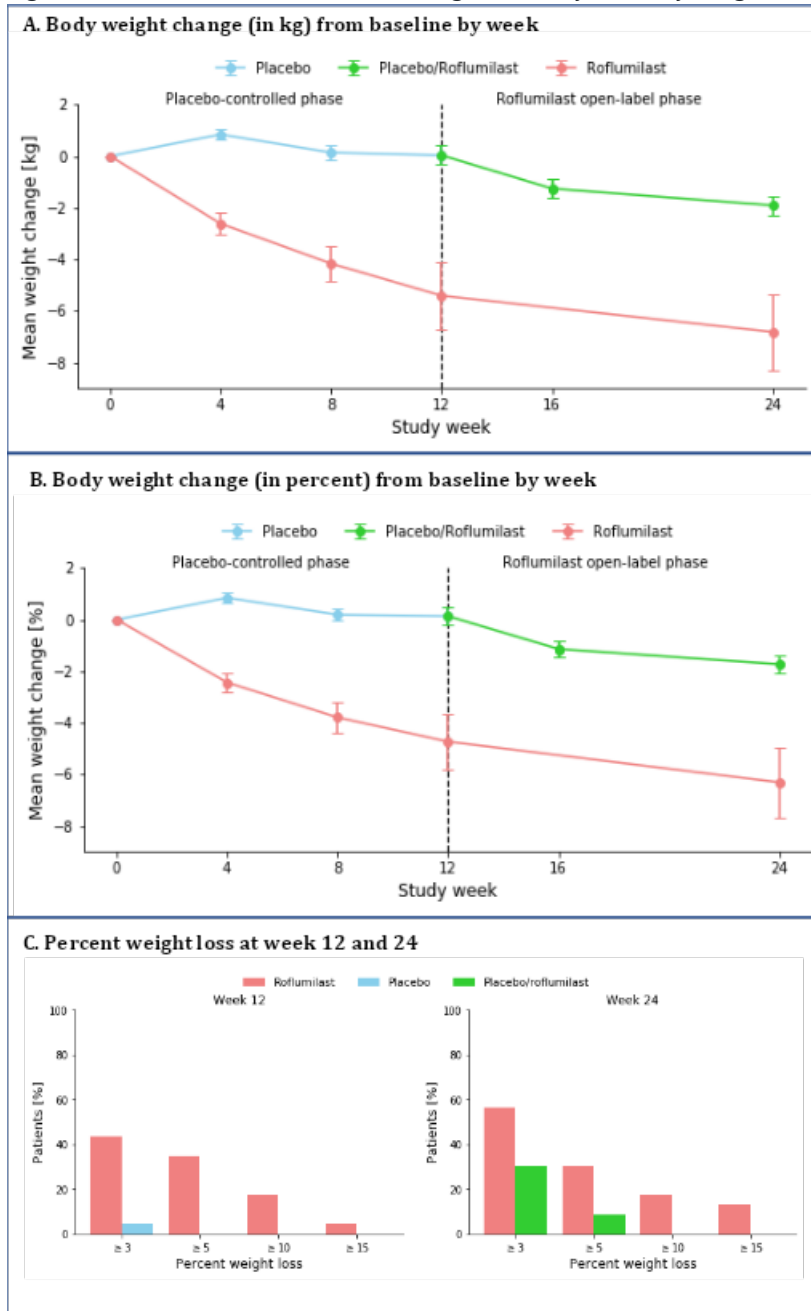
Weight loss and reduced appetite was observed after 24 weeks of oral roflumilast therapy in patients with psoriasis. With psoriasis being a chronic disease, strongly linked to overweight and obesity, the current findings support the growing evidence of roflumilast as an attractive, oral treatment alternative in, especially, overweight patients with moderate-to-severe plaque psoriasis.

**B. Body weight change (in percent) from baseline by week**

**A. Body weight change (in kg) from baseline by week**

**C. Percent weight loss at week 12 and 24**

Figure 1. Effect of oral roflumilast 500 µg once daily on body weight, as compared



with placebo