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**File: ■ IQP-GC-101 (Xanitrol™)
■ Weight Loss**

HC 061451-500

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RE: IQP-GC-101 Herbal Blend Reduces Body Weight Compared to Placebo

Chong P-W, Beah Z-M, Grube B, Riede L. IQP-GC-101 reduces body weight and body fat mass: A randomized, double-blind, placebo-controlled study. *Phytother Res.* May 2, 2014; [epub ahead of print]. doi: 10.1002/ptr.5158.

Successful weight loss is accomplished by decreasing energy intake and increasing energy expenditure. Pharmaceutical drug treatments for obesity focus on reducing caloric intake. This study evaluates IQP-GC-101 (Xanitrol™; InQpharm Europe Ltd; Hertfordshire, UK), which is hypothesized to reduce weight by inhibiting fatty acid synthesis and increasing thermogenesis and metabolism. IQP-GC-101 is a patented herbal blend that contains 650 mg garcinia (Malabar tamarind; *Garcinia cambogia*) extract standardized to 60% hydroxycitric acid (HCA), 100 mg green tea (*Camellia sinensis*) extract (15% epigallocatechin-3-gallate and 11% caffeine), 75 mg green coffee (unroasted *Coffea arabica*) extract (25% chlorogenic acid and 5% caffeine), and 25 mg banaba (*Lagerstroemia speciosa*) extract (5% corosolic acid). All 4 of these ingredients have been shown individually to have a role in weight loss in vivo. The purpose of this randomized, double-blind, placebo-controlled study was to evaluate the effect of IQP-GC-101 on body weight and body fat reduction in overweight Caucasians. The study design followed the guidance of the European Food Safety Authority which requires evidence of weight loss over a minimum of 12 weeks.

Subjects (n = 92, aged 18-60 years) were recruited via newspaper advertisement to participate in this study conducted at 2 centers in Berlin, Germany. Included subjects met the following criteria: Caucasian, body mass index (BMI) between 25 and 32 kg/m², stable body weight for 3 months before study enrollment, accustomed to eating 3 meals/day, committed to adhere to the diet plan, agreed not to use other weight loss products during the study period, and agreed to use birth control. The exclusion criteria were as follows: known hypersensitivity to the study ingredients; current or history of systemic or gastrointestinal diseases that may confound the outcomes of the study; pregnant or nursing; history of eating disorder; history of bariatric surgery; use of other weight loss products within 6 weeks before enrollment; change in dosage of estrogen, oral contraceptives, or thyroid hormone within the 3 months prior to enrollment; concurrent use of medication that might affect body weight (e.g., systemic

corticosteroids or antidepressants); and smoking cessation within 6 months prior to the start of the study.

The study began with a 2-week run-in phase where subjects were assessed as to whether they could comply with the diet and treatment (placebo). Those that could comply were randomized into the study. All subjects received diet counseling and a diet plan that provided them with a 500 kcal deficit diet (calculated on the basis of each individual's body weight, height, age, gender, and activity level). The diet provided 30% of the ingested energy as fat. A food diary was kept so that diet compliance could be monitored. Subjects took placebo or IQP-GC-101 3x/day for 12 weeks. The primary outcome measures were mean loss of body weight and body fat mass after 12 weeks of treatment. Secondary outcome measures were the change in fat free mass, waist circumference, and hip circumference measured at baseline and weeks 4, 8, and 12. The Control of Eating Questionnaire (COEQ) was used to measure hunger, fullness, the desire to eat different types of food, food cravings, mood, and alertness. Blood was drawn at baseline and at week 12 to assess full blood count, electrolyte levels, liver function, renal function, lipid metabolism, and carbohydrate metabolism.

At baseline, both groups were similar in terms of mean age, height, body weight, and body fat mass. At week 12, the IQP-GC-101 group had significantly greater weight loss than the placebo group (mean 4.98 lbs vs. 1.23 lbs, $P = 0.001$). At week 12, the IQP-GC-101 group had significantly greater body fat loss than the placebo group (mean 2.47 lb loss vs. 0.81 lb gain, $P = 0.001$). Accordingly, at week 12, the IQP-GC-101 group also had a significantly greater decrease in BMI than the placebo group (mean 0.78 kg/m² loss vs. 0.22 kg/m² loss, respectively, $P = 0.002$). Also, the IQP-GC-101 group had a significantly greater decrease compared to placebo in waist (mean 2 cm loss vs. 0.69 cm loss, respectively, $P = 0.006$) and hip circumference (mean 1.54 cm loss vs 0.64 cm loss, respectively, $P = 0.019$). There was no significant difference between groups on the COEQ or in laboratory parameters. All adverse events (AEs) were considered to be unrelated to treatment, and both groups had a similar frequency of AEs. Although adverse reaction reports have associated HCA with hepatotoxicity, there were no clinically relevant or statistically significant changes in liver enzyme or bilirubin levels observed in this study.

The authors conclude that IQP-GC-101 plus a slightly hypocaloric diet safely and significantly reduced body weight and body fat mass. They state that the degree of effectiveness in this study was on par with studies of other pharmaceuticals approved by the FDA for weight loss. All subjects lost weight initially; however, those in the placebo group stopped losing weight after 4 weeks and had gained fat mass by week 12. The authors hypothesize that after 4 weeks of loss, the body started to store fat as a form of homeostasis, and they infer that IQP-GC-101 reduced lipogenesis, thereby promoting fat oxidation and thermogenesis. A limitation of this study was that there was no control or monitoring of energy expenditure, diet compliance, or coffee/tea/caffeine intake. Longer duration studies with larger sample sizes and more rigorous controls are needed to determine whether the rate of weight loss is sustained and to better assess safety. Subjects should also be followed after treatment cessation to evaluate potential rebound effects.

—Heather S. Oliff, PhD

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