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Safety evaluation of p-synephrine following 15 days of oral administration to healthy subjects: A clinical study

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Abstract: Extracts of bitter orange (BOE, Citrus aurantium L.) and its primary protoalkaloid p?synephrine are extensively consumed as dietary supplements. p?Synephrine is also present in foods and juices prepared from various Citrus species. The safety of p?synephrine has been questioned as a result of structural similarities with ephedrine. This study assessed the cardiovascular (stimulant) and hemodynamic effects of BOE (49 mg p?synephrine) daily given to 16 healthy subjects for 15 days in a placebo?controlled, cross?over, double?blinded study. A physical evaluation by a cardiologist, as well as heart rates, blood pressures, and electrocardiograms were determined, and blood samples were drawn at baseline, and Days 5, 10, and 15. Serum levels for caffeine and p?synephrine were measured at 1 and 2 weeks. Subjects completed a 10?item health and metabolic questionnaire at baseline and on Day 15. No significant changes occurred in heart rate, electrocardiograms, systolic blood or diastolic pressures, blood cell counts, or blood chemistries in either the control or p?synephrine treated groups at any time point. No adverse effects were reported in response to the bitter orange (p?synephrine). Caffeine consumed by the participants varied markedly. Under these experimental conditions, BOE and p?synephrine were without stimulant (cardiovascular) and adverse effects.