



Efficacy of Slendesta™ Potato Protein Extract

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Key Conclusions

- **PI2, the active component in Slendesta Potato Protein Extract 5% Powder, has been shown to be effective in 11 clinical trials to date.**
- **When consumed as recommended, Slendesta Potato Protein Extract 5% Powder has resulted in statistically significant weight loss and reductions in waist and hip measurements.**
- **Slendesta Potato Protein Extract 5% Powder is thought to promote healthy weight loss through the stimulation of CCK release.**

Introduction

Obesity has become a worldwide epidemic (WHO 2003). Weight management products and programs are constantly evolving. Many of these can fail because dieters are unable to endure the commitment required to achieve their weight loss goals. Among the most common complaints of dieters is the constant feeling of hunger associated with reducing calorie intake. Because of this, Kemin Health has focused on providing a feeling of fullness to help dieters feel satisfied over longer periods of time while eating smaller portions. This feeling, known as satiety, happens naturally through a complex series of events initiated by the consumption of food and ending with signals to the brain that fullness has occurred (8). Foods are known to vary in their ability to stimulate satiety and one of the highest responses has been documented for potatoes (6).

Cholecystokinin (CCK), the best-studied satiety factor, is a natural signaling peptide released by the gut in response to food (8, 10). Once released, CCK acts on various target organs, resulting in signals to the brain, where it induces feelings of fullness and satiety. CCK cannot be consumed orally as it is degraded during the digestive process. A safe ingestible approach for dieters is needed.

Kemin Health has used patented technology to harness the CCK stimulating power of potatoes in Slendesta™ Potato Protein Extract (Slendesta). This extract contains potato proteinase inhibitors (PI2) that have been clinically shown to increase CCK release in humans. Proteinase inhibitors are a class of protein compounds commonly present in plant species, and are especially prevalent in potatoes and tomatoes. They represent the plants' natural defense mechanism against pests and infecting pathogens, help protect plant tissues from degradation by proteases, and control sprouting (11).

Specifically, PI2 was discovered in the 1960's by Dr. Clarence Ryan of Washington State University. Study of the molecule throughout the 1970's and 1980's led to the discovery of many unique properties, the greatest of which was that feeding PI2 to animals, and later humans, resulted in an increase in the release of CCK (9). This research is supported by several studies in the 1990's showing increased feelings of fullness, decreased food intake, and reduced post-meal blood sugar following PI2 consumption at levels ranging from 7.5 to 1500 mg (5, 12, 13, 15). To date, 13 clinical

trials have been conducted looking at the effects of PI2 on plasma CCK levels, glucose levels, hunger, satiety, and weight loss. Two of these trials showed trends of the efficacy of PI2 but were not significant. The remaining 11 studies all showed statistically significant effects of PI2 on the tested study outcomes (**Summarized in Table 1**).

A recent clinical study was conducted at Iowa State University with 45 subjects who took placebo, 15, and 30 mg PI2 (0, 300, and 600 mg Slendesta Potato Protein Extract 5% Powder*) by cross-over design at one week intervals. In this study, Slendesta taken before a meal resulted in significantly greater fullness, decreased motivation to eat, and decreased post-meal blood glucose levels compared to placebo. In addition, post-meal CCK levels were significantly increased, and remained elevated longer, relative to placebo (4).

In the largest randomized, double-blind, controlled clinical study conducted, 240 participants consumed either placebo, 15 or 30 mg PI2 (0, 300, or 600 mg Slendesta Potato Protein Extract 5% Powder*), 60 minutes before the two largest meals of the day for 12 weeks. Subjects taking Slendesta experienced statistically significant reductions in weight, waist and hips from baseline relative to placebo (2).

In the longest study conducted for a total duration of 20 weeks, subjects took 15 to 30 mg PI2 (300 to 600 mg Slendesta Potato Protein Extract 5% Powder*) twice daily before the two largest meals. During this open-label study, subjects lost an average 0.6 lbs per week and had statistically significant reductions of 6.5% in waist and 4% in hip measurements by 12 weeks (1).

Adult Daily Dosage Recommendations

Before Meals:

Take 300 mg Slendesta Potato Protein Extract 5% Powder (15 mg PI2) with a full glass of water approximately 60 minutes before the two largest meals (an additional dosage may be taken if desired, for a total of 600 mg (30 mg PI2)).

Throughout the Day:

Additional Slendesta may be taken if needed, to control snacking.

Additional Directions:

For use with a diet program. Consult a physician before starting any weight management or exercise program. Pregnant or lactating women should consult their physician before using this or any product.

Conclusion

CCK is a natural signaling peptide released by the gut in response to food and promotes satiety. Certain food components may be able to stimulate CCK release and this may be an explanation for the ability of potatoes to stimulate one of the highest satiety responses. Kemin Health has developed Slendesta in order to take advantage of the satiety induction mechanism of potatoes. Slendesta is a protein extract derived from potatoes using a patented process. To date, 11 clinical trials indicate that Slendesta is a safe and effective natural agent that promotes satiety and healthy weight loss. When consumed as recommended, Slendesta has resulted in statistically significant weight loss and reductions in waist and hip measurements, and may be useful for weight management.

* 300 to 600 mg Slendesta Potato Protein Extract 5% Powder in finished capsule form (Satise®) provided 15 to 30 mg PI2.

Table 1. Summary of Trials Indicating Efficacy of PI2

STUDY & SITE	DESIGN ^a & DURATION	NUMBER OF SUBJECTS	PI2 DOSE	RESULTS
Dana 2005 An open label clinical trial to evaluate a satiety aid for weight loss in overweight to obese healthy adults. Heartland Clinic (1)	O 12/20 weeks	28	15 or 30 mg ^b twice daily	Significant reductions in weight, waist, hips, and waist to hip ratio from baseline (p<0.001). Average 0.62 lbs (0.28 kg)/week weight loss with 6.5% waistline and 4% hip reductions over 12 weeks. Average 0.59 lbs (0.27 kg)/week weight loss with 15.9% waistline and 8.3% hip reductions over 20 weeks. No adverse events related to PI2 consumption observed.
Dana 2005 A randomized, double-blind, placebo-controlled clinical study demonstrates proteinase inhibitor II is a safe and effective tool for promoting weight reduction. Research Testing Laboratories (2)	RDC 12 weeks	240	15 or 30 mg ^b twice daily	Significantly greater reduction in body weight, waist, and hips than placebo (p<0.05). Dose response effect observed. Differences between control and active treatments were statistically significant. No adverse events related to PI2 consumption observed.
Dana <i>et al.</i> 2004 Weight loss with PI2 satiety aid (Mercy trial). Mercy Medical Center (3)	O 8 weeks	28	15 or 30 mg ^b twice daily + diet, exercise, counseling	85% of study completers lost weight; Average weight loss was 9.6 lbs (4.4 kg), ranging 3–30 lbs (1.4– 13.6 kg). No adverse events related to PI2 consumption observed.
Hu <i>et al.</i> 2004 A randomized, double-blind, single-center study to evaluate the efficacy of a satiety aid I. Hill Top Research (7)	RDC 6 weeks	83	15 or 30 mg ^b twice daily	Significant weight loss (1.42 lbs, p=0.0715); 1% hip reduction in 6 wks; Over 60% of subjects lost weight (max 11.3 lbs, 5.1 kg). No adverse events related to PI2 consumption observed.
Hu <i>et al.</i> 2004 The effectiveness of potato proteinase inhibitor II in promoting satiety in healthy human subjects (ISU trial). Iowa State University (4)	RDCCr 3 sessions: 4 hours, 1-wk intervals	45	15 or 30 mg ^b	Greater fullness, less motivation to eat than control at 2 hrs; Dose dependant decrease in blood glucose; Increased post-meal CCK at 60 and 120 min; CCK elevated longer with active treatment. No adverse events related to PI2 consumption observed.
Spreadbury <i>et al.</i> 2003 A proteinase inhibitor extract from potatoes reduces post-prandial blood glucose in human subjects. Des Moines University (14)	RDCCr 2.5 hours	39	7.5, 15, 30 mg ^b as capsules prior to a meal	15 and 30 mg doses significantly reduced post-meal blood glucose relative to placebo by 24% at 30 min after meal completion, and by 38% over 2 hours (p<0.05); No adverse events related to PI2 consumption observed.
Vasselli <i>et al.</i> 1999 Consumption of a pre-meal drink containing protease inhibitor from potatoes decreases hunger and increases fullness in overweight subjects following a meal. RWJ Medical Center (15)	RDCCr 3.5 hours	24	30 mg as a pre-meal drink	Significant decrease in hunger ratings by 30% compared to placebo (p<0.05); Increased fullness ratings. No adverse events related to PI2 consumption observed.
Spiegel <i>et al.</i> 1999 Effect of a pre-meal beverage containing a protease inhibitor from potatoes on satiety in dieting overweight women. Columbia U. (13)	4 weeks	21	60 mg as a pre-meal drink	Significant decrease in hunger ratings by 32% compared to placebo (p<0.01); Increased fullness ratings; Significant weight loss of 2 kg (4 lbs, p<0.001). No adverse events related to PI2 consumption observed.
Schwartz <i>et al.</i> 1994 Treatment with an oral proteinase inhibitor slows gastric emptying and acutely reduces glucose and insulin levels after a liquid meal in Type II diabetic patients. U TX Health Sci Ctr (12)	DCCr 2 hours, 1-wk intervals	6 Type 2 diabetics	1500 mg in a glucose-protein shake	Significant increase in plasma CCK 15 min after PI2 consumed (1.5pmol/L, p=0.05) compared to placebo; Decreased blood glucose; decreased insulin; Delayed gastric emptying; (p<0.05). No adverse events related to PI2 consumption observed.
Hill <i>et al.</i> 1990 Oral administration of proteinase inhibitor II from potatoes reduces energy intake in man. University of Leeds, UK (5)	RDC 1-wk intervals	11	1500 mg in a high protein soup	PI2 combined with soup resulted in a significantly greater decrease in meal intake (17.5%, p<0.02) relative to soup alone (3%) and control. No adverse events related to PI2 consumption observed.
Peikin <i>et al.</i> 1987 Oral administration of the protease inhibitor potato II stimulates release of cholecystokinin in man. RW Johnson Medical Center (9)	DC 1.5 hours	5	1000 mg as a pre-meal drink	CCK levels with PI2 consumption increased significantly before and after a meal compared to placebo (p<0.05). No adverse events related to PI2 consumption observed.

^a R = randomized, D = double-blind, C = controlled, Cr = crossover design, O = Open-label. ^b PI2 capsules were taken 30-60 minutes before meal consumption.

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